

# Exhibit 10

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE DISTRICT OF NEW JERSEY  
3                   CAMDEN VICINAGE

4                   \*\*\*\*\*

5                   IN RE: VALSARTAN, LOSARTAN, MDL No. 2875  
6                   AND IRBESARTAN PRODUCTS  
7                   LIABILITY LITIGATION                   Civil No.  
8                   19-2875  
9                   \*\*\*\*\* (RBK/JS)

10                  THIS DOCUMENT APPLIES TO ALL HON ROBERT B.  
11                  CASES                                   KUGLER

12                  \*\*\*\*\*

13                               - CONFIDENTIAL INFORMATION -  
14                               SUBJECT TO PROTECTIVE ORDER

15                               Remote Videotaped via Zoom  
16                   Deposition of MIN LI, Ph.D., commencing at 7:03  
17                   a.m. China Standard Time, on the 20th of  
18                   April, 2021, before Maureen O'Connor Pollard,  
19                   Registered Diplomat Reporter, Realtime  
20                   Systems Administrator, Certified Shorthand  
21                   Reporter.

22                               - - -

23                               GOLKOW LITIGATION SERVICES  
24                               877.370.3377 ph | 917.591.5672 fax  
                              deps@golkow.com

Page 2

1 APPEARANCES: ALL PARTIES APPEARED REMOTELY  
 2  
 3 MAZIE SLATER KATZ & FREEMAN, LLC  
 4 BY: ADAM SLATER, ESQ.  
 5 BY: CHERYLL A. CALDERON, ESQ.  
 6 BY: JULIA S. SLATER, ESQ.  
 7 BY: CHRISTOPHER GEDDIS, ESQ.  
 8 103 Eisenhower Parkway  
 9 Roseland, New Jersey 07068  
 10 973-228-9898  
 11 aslater@mazieslater.com  
 12 ccalderon@mazieslater.com  
 13 cgeddis@mazieslater.com  
 14 Representing the Plaintiffs  
 15  
 16 GOLDENBERG LAW, PLLC  
 17 BY: MARLENE J. GOLDENBERG, ESQ.  
 18 800 LaSalle Avenue, Suite 2150  
 19 Minneapolis, Minnesota 55402  
 20 612-436-5028  
 21 mjgoldenberglaw.com  
 22 Representing the Plaintiffs  
 23  
 24 KANNER & WHITELEY, LLC  
 25 BY: LAYNE HILTON, ESQ.  
 26 701 Camp Street  
 27 New Orleans, Louisiana 70130  
 28 504-524-5777  
 29 lhilton@kanner-law.com  
 30 Representing the Plaintiffs  
 31  
 32 HOLLIS LAW FIRM  
 33 BY: IRIS SIMPSON, ESQ.  
 34 BY: C. BRETT VAUGHN, ESQ.  
 35 8101 College Boulevard, Suite 260  
 36 Overland Park, Kansas 66210  
 37 800-701-3672  
 38 iris@hollislawfirm.com  
 39 Representing the Plaintiffs  
 40

Page 4

1 APPEARANCES (Continued):  
 2 GREENBERG TRAUER LLP  
 3 BY: KATE M. WITTLAKE, ESQ.  
 4 4 Embarcadero Center, Suite 3000  
 5 San Francisco, California 94111  
 6 415-655-1285  
 7 wittlakek@gtlaw.com  
 8 Representing the Defendants Teva  
 9 Pharmaceutical Industries, Ltd., Teva  
 10 Pharmaceuticals SA, Inc., Actavis LLC,  
 11 and Actavis Pharma, Inc.:  
 12  
 13 DUANE MORRIS, LLP  
 14 BY: NATHAN B. REEDER, ESQ.  
 15 30 South 17th Street  
 16 Philadelphia, Pennsylvania 19103  
 17 215-979-1164  
 18 nbreeder@duanemorris.com  
 19 Representing the Defendants Zhejiang  
 20 Huahai Pharmaceutical Co., Ltd.,  
 21 Princeton Pharmaceutical Inc., Huahai  
 22 U.S., Inc., and Solco Healthcare US,  
 23 LLC  
 24  
 25 DUANE MORRIS, LLP  
 26 BY: PATRICK C. GALLAGHER, ESQ.  
 27 1875 NW Corporate Boulevard  
 28 Boca Raton, Florida 33431  
 29 561-962-2131  
 30 pcgallagher@duanemorris.com  
 31 Representing the Defendants Zhejiang  
 32 Huahai Pharmaceutical Co., Ltd.,  
 33 Princeton Pharmaceutical Inc., Huahai  
 34 U.S., Inc., and Solco Healthcare US,  
 35 LLC  
 36

Page 3

1 APPEARANCES (Continued):  
 2 DALIMONTE RUEB STOLLER  
 3 BY: BEHRAM V. PAREKH, ESQ.  
 4 5790 Fleet Street  
 5 Carlsbad, California 92008  
 6 1-760-993-3595  
 7 Representing the Plaintiffs  
 8  
 9 MORGAN & MORGAN  
 10 BY: STEPHANIE JACKSON, ESQ.  
 11 BY: HANNAH FUJIMAKI, ESQ.  
 12 20 North Orange Avenue, Suite 1600  
 13 Orlando, Florida 32801  
 14 sjackson@forthepeople.com  
 15 hfujimaki@forthepeople.com  
 16 Representing the Plaintiffs  
 17  
 18 FLEMING NOLAN JEZ, LLP  
 19 BY: DAVID HOBBS, ESQ.  
 20 2800 Post Oak Boulevard  
 21 Houston, Texas 77056  
 22 713-621-7944  
 23 david\_hobbs@flaming-law.com  
 24 Representing the Plaintiffs  
 25  
 26 FARR LAW FIRM  
 27 BY: GEORGE T. WILLIAMSON, ESQ.  
 28 99 Nesbit Street  
 29 Punta Gorda, Florida 33950  
 30 941-639-1158  
 31 gwilliamson@farr.com  
 32 Representing the Plaintiffs  
 33  
 34 SLACK DAVIS SANGER, LLP  
 35 BY: JOHN R. DAVIS, ESQ.  
 36 6001 Bold Ruler Way, Suite 100  
 37 Austin, Texas 78746  
 38 512-795-8686  
 39 jdavis@slackdavis.com  
 40 Representing the Plaintiffs  
 41

Page 5

1 APPEARANCES (Continued):  
 2 DUANE MORRIS, LLP  
 3 BY: FREDERICK R. BALL, ESQ.  
 4 100 High Street  
 5 Boston, Massachusetts 02110  
 6 857-488-4229  
 7 frball@duanemorris.com  
 8 Representing the Defendants Zhejiang  
 9 Huahai Pharmaceutical Co., Ltd.,  
 10 Princeton Pharmaceutical Inc., Huahai  
 11 U.S., Inc., and Solco Healthcare US,  
 12 LLC  
 13  
 14 CIPRIANI & WERNER, P.C.  
 15 BY: JULIA H. FERTEL, ESQ.  
 16 450 Sentry Parkway  
 17 Blue Bell, Pennsylvania 19422  
 18 610-567-0700  
 19 jfertel@c-wlaw.com  
 20 Representing the Defendant Aurobindo  
 21 Pharmaceuticals  
 22  
 23 PIETRAGALLO GORDON ALFANO BOSICK &  
 24 RASPANTI, LLP  
 25 BY: JASON M. REEFER, ESQ.  
 26 One Oxford Centre  
 27 Pittsburgh, Pennsylvania 15219  
 28 412-263-1840  
 29 jmr@pietragallos.com  
 30 Representing the Defendant Mylan  
 31 Pharmaceuticals, Inc.  
 32  
 33 Also Present: Phil Hughes  
 34 Videographer: Judy Diaz  
 35

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4	Direction to Witness Not to Answer
5	PAGE LINE
6	None.
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9	PAGE LINE
10	None.
11	35 14
12	Stipulations
13	PAGE LINE
14	None.
15	Questions Marked Highly Confidential
16	PAGE LINE
17	None.
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22	
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1	PROCEEDINGS
2	
3	THE VIDEOGRAPHER: We are now
4	on the record.
5	My name is Judy Diaz, I am a
6	legal videographer for Golkow
7	Litigation Services.
8	Today's date is April 20, 2021,
9	and the time is 7:03 a.m.
10	This remote video deposition is
11	being held in the matter of Valsartan,
12	Losartan, and Irbesartan Products
13	Liability Litigation MDL.
14	The deponent is Min Li, Ph.D.
15	All parties to this deposition
16	are appearing remotely and have agreed
17	to the witness being sworn in
18	remotely.
19	All counsel will be noted on
20	the stenographic record.
21	The court reporter is Maureen
22	Pollard, and will now swear in the
23	witness.
24	///

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1 MIN LI, Ph.D.,  
2 having been duly remotely sworn, was examined  
3 and testified as follows:  
4 EXAMINATION  
5 BY MR. SLATER:  
6 Q. Good evening.  
7 A. Good evening. Yeah, I'm here.  
8 Actually, it's morning here.  
9 Q. Okay. We're here to take your  
10 deposition. Do you understand that's the  
11 purpose of this proceeding?  
12 A. Sure. Yes.  
13 Q. Have you ever been deposed  
14 before?  
15 A. No.  
16 Q. This is a sworn proceeding in  
17 the United States District Court.  
18 Do you understand that you're  
19 now under oath and must tell the truth?  
20 A. Yes, I understand.  
21 Q. If for any reason you are asked  
22 a question and don't feel like you either  
23 understand it or can answer it truthfully and  
24 accurately for any reason based on how the

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1 question was asked or what was asked, just  
2 tell me.  
3 A. Sure.  
4 Q. It may be that I mispronounce a  
5 word or use scientific jargon incorrectly.  
6 Whatever the case may be, you can just let me  
7 know what's unclear, and I can try to  
8 rephrase the question. Okay?  
9 A. Okay. Great.  
10 Q. During the course of the  
11 deposition, there will be objections and  
12 discussion between the attorneys. That's  
13 normal. That's people preserving the record  
14 for future use in the court.  
15 It's not something that should  
16 throw you off; I just want you to know that  
17 might happen, okay?  
18 A. Okay.  
19 Q. And certainly there's no reason  
20 why any objection or statement by any  
21 attorney would be any sort of a prompt for  
22 you to say anything or not say anything.  
23 It's just the attorneys discussing their  
24 legal positions on different things.

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1 So certainly that's not  
2 something you would ever want to be doing, is  
3 taking a cue from an attorney's objection or  
4 anything they say.  
5 Do you understand that?  
6 A. Okay.  
7 Q. What is your current title?  
8 A. I'm the vice-president for  
9 analytical operation for Huahai  
10 Pharmaceutical Company, or also known as ZHP,  
11 particularly, you know, in this case.  
12 MR. SLATER: Let's put up  
13 Exhibit 291, please, Cheryll.  
14 (Whereupon, Exhibit Number  
15 ZHP-291 was marked for  
16 identification.)  
17 MR. SLATER: Great. Thank you.  
18 BY MR. SLATER:  
19 Q. On the screen is the notice to  
20 take your deposition. Have you seen this  
21 document before?  
22 A. Yes. Actually, I also have a  
23 copy, yes.  
24 Q. Oh, you have a copy in front of

Page 13

1 you?  
2 A. Yes.  
3 Q. Okay. Did you familiarize  
4 yourself with the topics that you're going to  
5 be questioned about tonight --  
6 A. Yes.  
7 Q. -- and for the next several  
8 days?  
9 A. Yes, I think so. You know, I  
10 try my best to be familiarize myself, yes.  
11 Q. Did you prepare for this  
12 deposition?  
13 A. Oh, yes.  
14 Q. What did you do to prepare for  
15 the deposition?  
16 A. Mostly receiving, you know,  
17 trainings from my, you know, lawyers.  
18 And also I've talked to various  
19 peoples, you know, because a lot of details I  
20 need to, you know, find out from -- basically  
21 from my level, you know. Typically I have  
22 not been involved in too many details,  
23 particularly nontechnical issues.  
24 Q. You said that you spoke with

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1 your attorneys; I think you called it  
2 training from your lawyers.  
3 Who was it that you spoke with?  
4 A. You know, here Patrick, and  
5 also Rick, Nason. Mostly, you know, those  
6 three. Sometimes, you know, there's other,  
7 like Seth.  
8 Q. Did you speak to any attorneys  
9 in China in preparing for the deposition?  
10 A. No. Because I'm a US citizen,  
11 I don't think it's legally obligated for me  
12 to talk to anybody, you know, or any lawyer,  
13 you know, in China.  
14 Q. Did anybody tell you that?  
15 A. Yeah. I mean, you know, the  
16 lady, you know, in the general -- you know,  
17 in the president office, you know, she's  
18 basically managing this. You know, that's  
19 what she told me, because she's being  
20 basically, you know, get in touch with, you  
21 know, the Chinese lawyer for my Chinese  
22 colleagues, because we want to make sure, you  
23 know, right, we have to be basically abide  
24 by, you know, you know, the Chinese law as

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1 well, because otherwise, you know, if you  
2 have any procedural violation, you know, you  
3 may get into big trouble.  
4 Q. Who did you speak with in the  
5 president's office? You said you spoke with  
6 a woman about the deposition. Who was that?  
7 A. Maggie, yeah. Maggie Kong.  
8 Yeah, yeah.  
9 Q. Can you spell her name, please?  
10 A. Last name is K-O-N-G. She  
11 usually goes by her English name, you know,  
12 Maggie, but also her Chinese name is  
13 Xiaofong, Xiaofong Kong.  
14 Q. And when did you speak with her  
15 about the deposition?  
16 A. That was long time. You know,  
17 I think in the very early phase. I don't  
18 remember exactly, you know, how long. Maybe,  
19 like, for several months.  
20 Q. Was that the first time you  
21 spoke with anybody about this deposition?  
22 A. I don't think so.  
23 Q. Who was the first person you  
24 ever spoke to about the deposition?

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1 A. I really don't remember.  
2 Probably, I would assume most likely her, but  
3 I, you know, because it's such a long period,  
4 and I really cannot tell, like, who is  
5 exactly the first person, to be honest with  
6 you. I mean, I don't have photographic, you  
7 know, memory.  
8 Q. When you say it's been "such a  
9 long period," can you estimate how long ago  
10 it was when you first spoke with someone  
11 about this deposition?  
12 A. Maybe six months. I don't  
13 know. I mean, it's just a very rough  
14 estimate.  
15 Q. Could it have been a year ago?  
16 A. I mean, if you're talking  
17 about, you know, you know, starting  
18 collecting, you know, the document, yeah, I  
19 would say, yeah, that's about, you know, at  
20 least about a year ago, yes.  
21 Q. When did you first find out  
22 your deposition was going to be taken?  
23 A. I think sometime last year,  
24 because I -- you know, you know, she told me

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1 I will be one of the -- you know, the  
2 witness, you know, will be, you know, giving  
3 the testimony. Sometime last year.  
4 Q. So you think it was maybe a  
5 year ago?  
6 A. I wasn't sure. As I said, I  
7 wasn't sure exactly, you know, but sometime  
8 last year, okay?  
9 Q. Well, right now it's April 19th  
10 here in the States, so are we talking last  
11 April? Are we talking last summer? Are we  
12 talking before April? Do you recall?  
13 A. As I said, I don't have  
14 accurate recollection.  
15 Q. Do you have a calendar that you  
16 keep that would show you when you were first  
17 notified that you were going to be deposed?  
18 A. I don't keep that particular  
19 calendar, like particularly when was the  
20 first day that I received the notice.  
21 Because I -- you know, from my perspective,  
22 you know, you know, that's not important. I  
23 mean, the important thing is I know what's  
24 the date and I need to prepare.



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1 Q. I wasn't asking you what was  
 2 important. I'm just asking you if you  
 3 remember when it was.  
 4 A. I don't remember exactly date.  
 5 I told you, you know, a few times already.  
 6 Q. Did you receive an e-mail about  
 7 this deposition back in the beginning?  
 8 A. Yeah, I think so. Yeah, I  
 9 received an e-mail. You know, if I go back  
 10 to my, you know, you know, e-mail, I mean, I  
 11 may be able to tell you tomorrow, you know.  
 12 You know, after this session I can, you know,  
 13 if you really wanted to have that.  
 14 Q. That would be great if we could  
 15 have an understanding of when you first  
 16 learned about --  
 17 A. Okay.  
 18 MR. GALLAGHER: Object to the  
 19 extent that -- we'll take it under  
 20 advisement. Object to the extent it  
 21 calls for any privileged information.  
 22 BY MR. SLATER:  
 23 Q. You said the first person you  
 24 ever spoke to about being deposed was Maggie

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1 Kong, is that correct?  
 2 A. I would say likely.  
 3 Q. Who else in your company have  
 4 you spoken to about the deposition?  
 5 A. I mean, what do you mean by --  
 6 you know, speaking about what?  
 7 Q. Anything having to do with the  
 8 deposition, either the fact of the  
 9 deposition, what you were going to testify  
 10 to, how to conduct yourself, obtaining  
 11 information to testify. Anything connected  
 12 to the deposition.  
 13 A. I talked to, you know, people,  
 14 right? Particularly people who travel, you  
 15 know, to, you know, you know, to Macao,  
 16 right?  
 17 I talked to them about  
 18 logistics, you know, about, you know, the  
 19 procedural, you know, all the details, you  
 20 know, the purposes just for me, you know, to  
 21 be able to getting to Macao and to be  
 22 participate in this, you know, testimony, you  
 23 know. I just want to make sure, you know,  
 24 things will be done as arranged, right?

Page 20

1 And also talk to, like, Peng  
 2 Dong, you know, you know, Mr. Peng Dong,  
 3 quite early on during, you know, you know, at  
 4 the early phase of the preparation because I  
 5 asked him something about, you know, the  
 6 early -- you know, during the early stage,  
 7 you know, you know, how that original, you  
 8 know, you know, process, you know, was  
 9 developed, you know, you know, the so-called  
 10 zinc chloride, you know, process.  
 11 Q. Well, we'll go back through the  
 12 names and what you spoke to them about, but  
 13 let's try to get the list of names of people  
 14 from your company you spoke to. So far we  
 15 have Maggie Kong and we have Peng Dong.  
 16 Who else from your company did  
 17 you speak to with regard to anything  
 18 connected to the deposition?  
 19 A. I also talked to Qiangming Li,  
 20 you know, as I said, mostly about logistics,  
 21 getting into, you know, the hotel, you know,  
 22 everything. Yeah.  
 23 Q. Who else?  
 24 A. Who else? And also talked to

Page 21

1 one of the staff under, you know, Qiangming  
 2 Li and asking about some of the specifics.  
 3 Q. Who was that person?  
 4 A. His name is Jun Wang.  
 5 Q. Who else from your company have  
 6 you spoken to with regard to the deposition?  
 7 A. I think that's about it.  
 8 Q. You said earlier you'd spoken  
 9 to people in order to get some background  
 10 information in order to testify.  
 11 Who were the people that you  
 12 spoke to to get that background information  
 13 to be able to testify on the topics you were  
 14 designated on?  
 15 A. The background -- well,  
 16 basically when I say "background" is, you  
 17 know, actually I'm referring to, you know, to  
 18 that particular topic regarding, you know,  
 19 that process change, right?  
 20 So with that regard I was  
 21 talking to, you know, Mr. Peng Dong during  
 22 the early phase, you know, of the  
 23 preparation.  
 24 Q. What else did you talk to Peng

Page 22

1 Dong about besides the process change?  
2 Anything?  
3 A. No, that's it.  
4 Q. What specifically did you  
5 discuss with Mr. Dong regarding --  
6 A. I just -- I was asking him, you  
7 know, who basically was involved, you know,  
8 in that process change.  
9 He said he was not clear  
10 because, you know, he probably was not  
11 involved, you know, during that process, I  
12 mean.  
13 Q. So you spoke to Peng Dong about  
14 the process change, you asked him who was  
15 involved, and he said he didn't know because  
16 he wasn't involved, and that was the  
17 conversation?  
18 A. Yeah, pretty much, yeah.  
19 Basically, you know, I was asking him, like,  
20 who basically was the original sort of, like,  
21 you can call, like, inventor or whatever,  
22 like who developed that process.  
23 Q. And what did he tell you?  
24 A. He said, you know, you know,

Page 23

1 you know, he didn't know.  
2 Q. Can you tell me who was the  
3 inventor of the process change, the zinc  
4 chloride process change?  
5 A. Well, the -- you know, from the  
6 document, right, from the document, you know,  
7 at least some of the document, I know the  
8 technology was originated from SynCore, okay,  
9 which is a subsidiary of Huahai  
10 Pharmaceutical.  
11 But I was just asking him who,  
12 you know, that individual, like specifically  
13 who that individual was.  
14 Q. And he didn't know?  
15 A. He didn't -- yeah, he didn't  
16 know.  
17 Q. Did you ask anybody else?  
18 A. No.  
19 Q. Did you speak to anybody from  
20 SynCores?  
21 A. No.  
22 Q. Why not?  
23 A. I mean, for me, you know, I  
24 mean, there's no need for me to go more

Page 24

1 deeper, you know, because I'm not a, you  
2 know, a process chemist.  
3 MR. GALLAGHER: I'm going to  
4 object to the line as outside the  
5 scope of the 30(b)(6) topics, but  
6 certainly --  
7 MR. SLATER: Patrick, you're  
8 saying that my questioning about how  
9 he prepared himself to testify for the  
10 30(b)(6) topics is outside the scope  
11 of the 30(b)(6) topics?  
12 MR. GALLAGHER: No, no.  
13 MR. SLATER: Because that's  
14 what I'm doing.  
15 MR. GALLAGHER: Proceed.  
16 BY MR. SLATER:  
17 Q. How long did this discussion  
18 with Peng Dong take?  
19 A. Just very briefly over the  
20 phone, yeah.  
21 Q. Okay. How long did it take?  
22 A. Maybe five, ten minutes.  
23 Q. So let me -- rephrase.  
24 Did you say you also spoke to

Page 25

1 Mr. Qiangming Li?  
2 A. Yes. About the logistics,  
3 traveling into Macao.  
4 Q. Did you talk to Qiangming Li  
5 about anything substantive about your  
6 testimony?  
7 A. No.  
8 Q. Did you ask him any questions  
9 about something you might testify about?  
10 A. No.  
11 Q. The staff member Jun Wang, when  
12 did you speak to that person?  
13 A. Not Jun Wang. It's Jun, yeah.  
14 J -- Jun Wang or Jun Wang.  
15 Q. I'll ask it again.  
16 When did you speak to Jun Wang?  
17 A. Just a few days, like, let me  
18 see, just two, three days before I came over  
19 to Macao, yeah, because I just wanted to try  
20 to clarify some of the, you know, you know,  
21 chronology of the events, you know, for some  
22 of the customers, you know, you know, or  
23 their discussion.  
24 Because, you know, he was the



<p style="text-align: right;">Page 26</p> <p>1 main person doing the analytical                  2 investigation from the QC side, so I just,                  3 you know, tried to ask him some of those, you                  4 know, you know, you know, details like, you                  5 know, how many customers, you know, you know,                  6 like been having this.                  7 You know, some of those, you                  8 know, early on we characterized them as like                  9 technical exchange, right, and then later on,                  10 you know, it's being formally characterized                  11 as a customer complaint.                  12 Well, basically, you know,                  13 talking about, you know, these unknown peaks,                  14 you know. Yeah. So I was just trying to,                  15 you know, you know, find out who -- like                  16 when, you know, like the -- you know, what                  17 the, you know, their question, you know, was.                  18 Q. When you say "the unknown                  19 peaks," do you mean the unknown peaks that                  20 later were identified as nitrosamine peaks?                  21 A. No. Actually all of the peaks,                  22 all of the peaks, right, after I review, you                  23 know, those documents, right, all of the                  24 peaks people talking about between Huahai's</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. When you say that it can                  2 co-elute with a background peak, are you                  3 talking about the toluene peak?                  4 A. No. Actually, there was one                  5 little peak after the toluene peak.                  6 Q. And the little peak after the                  7 toluene peak turned out to be the nitrosamine                  8 peak, correct?                  9 A. Oh, no, no. Actually, that                  10 peak -- well, that peak in the background,                  11 okay -- it's a little bit complicated. Okay.                  12 In the background -- so that peak is also                  13 eluted in the blank injection, okay?                  14 And then in the sample                  15 injection, this peak turns out -- if I                  16 remember correctly, this peak turns out to be                  17 n-butyl acetate, okay?                  18 So that's the peak -- that's                  19 the peak, you know, eluting after the toluene                  20 peak. Okay. So NDMA would elute on the                  21 shoulder, or sometimes may even completely                  22 co-elute with this peak.                  23 Q. When did you speak to Jun Wang?                  24 You said two to three days before you came to</p>
<p style="text-align: right;">Page 27</p> <p>1 customer and, yeah, all of those peaks, you                  2 know, that discuss that specifically they're                  3 not nitrosamine.                  4 I mean, obviously, I mean, you                  5 know, you know, retrospectively maybe one of                  6 the tiny -- you know, now we know, right,                  7 nitrosamine, you know, you know, it could                  8 co-elute with one of the backgrounds. But                  9 that's only, you know, you know, after, you                  10 know, the facts, you know, after.                  11 And then when you spike, you                  12 know, the standard sample or reference sample                  13 of the NDMA, you know, with a very high,                  14 like, concentration, then you -- you know,                  15 retrospectively you can say, hey, you know,                  16 the NDMA could co-elute, you know, after, you                  17 know -- actually on the shoulder of the one                  18 background peaks.                  19 But all of the -- you know, all                  20 of the peaks, you know, people were talking                  21 about, you know, retrospectively we know, you                  22 know, they are not NDMA or anything, you                  23 know -- you know, any other, you know,                  24 nitrosamines.</p>	<p style="text-align: right;">Page 29</p> <p>1 Macao. When was that?                  2 A. I came here on the 18th. Yeah.                  3 So it would be like, you know, around the                  4 16th, yeah.                  5 Q. The 16th would have been                  6 Friday?                  7 A. Yes, is 16 Friday? Let's see.                  8 Yeah, it's Friday, yes.                  9 Q. How long did you talk to Jun                  10 Wang about this deposition?                  11 A. It's probably 15, 20 minutes.                  12 Q. Did you review any documents to                  13 prepare for the deposition?                  14 A. Did I review any documents?                  15 Yes.                  16 Q. What did you review to prepare                  17 for the deposition?                  18 MR. GALLAGHER: Let me just --                  19 give me a minute, Min.                  20 To counsel not to disclose the                  21 substance of conversations that you                  22 had with attorneys.                  23 MR. SLATER: I didn't ask                  24 anything about attorneys.</p>

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1 THE WITNESS: Okay.  
2 MR. GALLAGHER: You asked about  
3 documents he reviewed, which he may  
4 have done with attorneys, so I'm  
5 just -- he can answer the question.  
6 I'm just going to caution him not to  
7 disclose the substance of  
8 conversations he had with attorneys.  
9 Please answer the question.  
10 A. I mean, there are quite a few  
11 documents here. Yeah, for example, some of  
12 the --  
13 BY MR. SLATER:  
14 Q. Let me ask it very clearly.  
15 A. You know, regarding, you know,  
16 unknown peak investigations. And also like  
17 ICH documents, you know, and also some of  
18 our -- like SOPs, and also the deviation  
19 investigation reports. You know, I mean,  
20 there's a lot of stuff.  
21 Q. Were you reading these  
22 documents for the first time?  
23 A. No. Many of -- I mean, some of  
24 those, you know, obviously I read before, you

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1 know, like SOPs, ICH documents, you know.  
2 But some obviously, you know, that I read,  
3 you know, the very first time.  
4 Q. You met with counsel how many  
5 times to prepare for deposition?  
6 A. Oh, I think like five, six  
7 times.  
8 Q. When is the first time you  
9 spoke to counsel about the deposition?  
10 A. I don't recall.  
11 Q. Give me your best estimate.  
12 A. Let's say -- I have to think  
13 about it. It's -- you know, in the beginning  
14 it was like a weekly training, and then we --  
15 you know, you know, before I came we skipped  
16 one, so I don't know how many.  
17 Let's say -- hypothetically  
18 let's say six times, right? So the fifth  
19 time will be like a half-month ago, right?  
20 So then I have another -- yeah,  
21 so roughly like one and a half months ago  
22 starting. But don't hold me accountable, you  
23 know, if it's a little bit off, you know.  
24 But as I said, it's in the ball park.

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1 Q. You said "before I came." What  
2 were you referring to?  
3 A. Well, the 18th of April, I mean  
4 this last Sunday, came to Macao.  
5 Q. So before you came to Macao, I  
6 wasn't clear, how many times did you say you  
7 spoke to counsel?  
8 A. Totally, as I said, like five  
9 or six times.  
10 Q. When was the first time you  
11 spoke to counsel in connection?  
12 A. As I told you, by rough  
13 estimation, it probably was like maybe a  
14 month and a half ago. But as I said, it  
15 could be two months, you know. But it just  
16 seemed like a ball park.  
17 Q. How much time did you spend in  
18 those meetings with counsel?  
19 A. Usually I would say like about  
20 two hours roughly, average.  
21 Q. Okay. Looking at the  
22 deposition right now, the deposition  
23 notice -- rephrase.  
24 Looking at the deposition

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1 notice, let's go to the -- actually, you have  
2 it in front of you, right?  
3 A. Yeah.  
4 Q. On the second-to-last page of  
5 the deposition notice, there was a request  
6 for your most recent resume/curriculum vitae  
7 and your LinkedIn profile.  
8 A. Uh-huh. I already provided it.  
9 Q. And those are the most recent  
10 versions of both?  
11 A. Yes.  
12 Q. This also asked for  
13 the complete production of any relevant  
14 custodial documents for you, "including those  
15 maintained on personal computers or  
16 electronic devices, to the extent not  
17 produced prior."  
18 Are you producing any documents  
19 in connection with the deposition at this  
20 time?  
21 A. No.  
22 Q. You started working with ZHP in  
23 2014, right?  
24 A. Yes. September of 2014, yes.

<p style="text-align: right;">Page 34</p> <p>1 Q. Were you given any sort of a                  2 computer at that time to do your work for                  3 ZHP?                  4 A. Yes.                  5 Q. What type of computer were you                  6 given when you started?                  7 A. Originally it's a ThinkPad,                  8 Lenovo ThinkPad, but that computer broke                  9 down. Now I have a Microsoft, like what,                  10 ProBook.                  11 Q. You said you were given a                  12 Lenovo ThinkPad when you started, and then it                  13 broke. When did it break?                  14 A. When did it break. That's a                  15 very good question. It broke during --                  16 actually during a trip. I don't remember                  17 exactly.                  18 When did it break. Probably                  19 somewhere between 2017 to 2018, but, you                  20 know, I don't have an accurate, you know,                  21 recollection exactly, like, which year.                  22 Q. When your computer broke, did                  23 you notify your company that you needed a new                  24 computer?</p>	<p style="text-align: right;">Page 36</p> <p>1 in writing, and we'll take it under                  2 advisement.                  3 BY MR. SLATER:                  4 Q. When you said the computer                  5 broke on a trip, what happened to the                  6 computer?                  7 A. It just could not start, so I                  8 think eventually it turns out to be, you                  9 know, a hard drive failure.                  10 Q. What happened to the data that                  11 was on the computer?                  12 A. I would say, according to the                  13 IT guys -- well, quite a few documents                  14 actually became permanently damaged, but the                  15 majority of them was able to be restored,                  16 yeah.                  17 Q. You said documents were                  18 permanently damaged?                  19 A. Some of the documents, yeah,                  20 because of the hardware, you know, failure.                  21 Q. What types of documents were                  22 permanently damaged?                  23 A. Well, it's -- you know, there's                  24 different kinds.</p>
<p style="text-align: right;">Page 35</p> <p>1 A. Oh, yeah, mm-hmm.                  2 Q. Who did you notify?                  3 A. IT.                  4 Q. And they got you a new                  5 computer?                  6 A. Yes.                  7 Q. There would be a record within                  8 the company of you asking for a new computer                  9 and getting that computer. I assume                  10 something like that gets documented, right?                  11 A. Oh, sure, sure, uh-uh.                  12 Q. So if we need to know when your                  13 computer broke and when you got your new                  14 computer, the company should be able to                  15 provide that information, right?                  16 A. Yeah. If I ask, they should be                  17 able to provide, yes.                  18 MR. SLATER: Counsel is going                  19 to ask me to send an e-mail or                  20 something after the deposition to                  21 confirm the request, but that's going                  22 to be another one of the things we're                  23 going to request.                  24 MR. GALLAGHER: Please put it</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. Well, tell me, please, which                  2 ones?                  3 A. Like some of those, like,                  4 research papers, you know, some of those                  5 research, you know, you know, investigation                  6 report. And even, you know, some personal,                  7 you know, like pictures.                  8 Q. Was your computer backed up                  9 periodically?                  10 A. What do you mean, "backed up"?                  11 Like backed up to, like, an external drive?                  12 Q. I mean backed up so that the                  13 data was held in a separate location so that                  14 if your computer stopped working, the data                  15 wouldn't be lost.                  16 A. I -- you know, I didn't do                  17 that.                  18 Q. Is there any protocol in your                  19 company to back up computers periodically?                  20 A. Well, for important documents,                  21 you know, you know, the company have archive,                  22 so I don't need to, you know, you know, to                  23 archive like, you know, by myself.                  24 Q. How about your e-mails? Were</p>

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1 any of your e-mails lost when your computer  
2 broke?

3 A. No. E-mail, you know, it's  
4 always there, e-mail, you know, because it's  
5 always in the server.

6 That's, you know, that's what  
7 the IT -- you know, at least, you know, it  
8 will be preserved according to the company  
9 policy, you know, for as long as the company  
10 policy, you know, you know, would allow.

11 Q. What does the company policy  
12 require?

13 A. I don't have the specifics.

14 Q. You've been there since 2014.  
15 Is it your understanding that all the e-mails  
16 you've sent or received have been backed up  
17 or held on a server?

18 A. As I said, yeah, I mean, as  
19 long as, you know, you know, the company, you  
20 know, policy says, you know, how long it will  
21 keep, you know, in company server, it will be  
22 there. You know, so that regardless, you  
23 know, my personal computer's failure, it will  
24 be there.

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1 Q. Has there ever been a time  
2 since your computer broke where you realized  
3 that a document or any data was lost and you  
4 couldn't retrieve it, couldn't find it?

5 A. No. I always be able to  
6 retrieve, you know, from either my e-mail or  
7 from, you know, you know, company's archive,  
8 or from my colleagues, you know.

9 Q. The ThinkPad, is that a desktop  
10 or is that a laptop or something else?

11 A. Laptop. Nobody use desktop  
12 anymore, as far as I know, I mean, you know,  
13 for personal use.

14 Q. Well, in your work at ZHP, have  
15 you had a desktop computer in addition to the  
16 laptop?

17 A. No.

18 Q. Never had a desktop computer?

19 A. I think it's totally obsolete  
20 for the purpose, you know, you know, people  
21 doing office work. I mean, at least for me,  
22 I mean.

23 Q. I'd like to be a little more  
24 precise on the timing of when your computer

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1 broke, if you can recall. Otherwise we're  
2 obviously going to make our request, but it  
3 might help.

4 Did it occur in -- you said --  
5 well, rephrase.

6 With regard to when your  
7 computer broke, was that in 2017, or was that  
8 in 2018?

9 A. As I said, just around that  
10 period. I need to -- I need to -- you know,  
11 as I said, I'll talk to my IT guys, you know,  
12 you know. They will have the record, right,  
13 when the replacement happened.

14 Q. When you -- rephrase.

15 When your Lenovo ThinkPad  
16 broke, did you say that you got a Microsoft  
17 ProBook --

18 A. Yes.

19 Q. -- as your new computer?

20 A. Yes.

21 Q. And that's another laptop?

22 A. Yes.

23 Q. Is that the same computer, the  
24 one you use today?

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1 A. Yes.

2 Q. So --

3 A. Well, no. I'm sorry, no. Hold  
4 on, hold on. This is -- no. This is the  
5 company's -- you know, you know, the solely  
6 dedicated computer, you know, right? What  
7 we're talking about right now, okay?

8 What I'm saying is, you know,  
9 you know, the PC or the laptop I'm using for  
10 my business, right, or company business,  
11 yeah, is a Microsoft, you know, ProBook,  
12 okay?

13 Q. During the time you've worked  
14 at ZHP, have you also owned other computers  
15 for personal use, other than the Lenovo  
16 ThinkPad and the Microsoft ProBook?

17 A. No.

18 Q. Did you use the ThinkPad and  
19 the ProBook -- rephrase.

20 Did you use the Lenovo ThinkPad  
21 not only for company business, but also for  
22 personal e-mail?

23 A. No, I don't think so. I mean,  
24 only maybe for -- let me see. Did I -- for

<p style="text-align: right;">Page 42</p> <p>1 personal -- I cannot guarantee, like, I                  2 haven't, like, receive a single, like, a                  3 personal e-mail. But I can say usually I                  4 don't use that for, you know, you know, for                  5 personal e-mails, okay.                  6 Q. What computer -- during the                  7 time -- rephrase.                  8 During the time you had the                  9 Lenovo ThinkPad, what computer did you use                  10 for your personal e-mails?                  11 A. Well, the personal e-mail --                  12 let's see. The personal e-mail -- well, I                  13 used the personal e-mail, you know, through                  14 the web, right, to access my personal e-mail.                  15 I mean is that, is -- to me,                  16 you know, you know, I wasn't sure that                  17 constitutes as the personal use of the                  18 Microsoft, you know, you know, you know, like                  19 the ProBook.                  20 Q. Let's try to take this one step                  21 at a time.                  22 When you had the Lenovo                  23 ThinkPad, you had a ZHP e-mail address,                  24 right?</p>	<p style="text-align: right;">Page 44</p> <p>1 try to send an e-mail to you to your work                  2 e-mail, and because "Min Li" is in your                  3 e-mail address, it would come to your                  4 personal e-mail?                  5 A. No, no, no, no. What I'm just                  6 trying to say is sometimes if I, you know,                  7 you know, try to, like -- you know, sometimes                  8 when I send an e-mail I, you know, also maybe                  9 want to cc myself.                  10 And so when I type, you know,                  11 my company's, you know, you know, e-mail                  12 address, you know, my personal e-mail                  13 address, you know, sometimes may accidentally                  14 be typed in, you know.                  15 Q. On the Microsoft ProBook, have                  16 you used your personal e-mail?                  17 A. I also, as I said, access my                  18 personal e-mail accounts from time to time.                  19 You know, that's pretty much, you know, you                  20 can say that I use, you know, that computer                  21 for personal use.                  22 Q. Did you use your personal                  23 e-mail on the Microsoft ProBook for business                  24 e-mails?</p>
<p style="text-align: right;">Page 43</p> <p>1 A. Yes, uh-huh.                  2 Q. Did you also have a personal                  3 e-mail address not related to your work?                  4 A. Yes, I have a personal e-mail                  5 address.                  6 Q. Did you use that personal                  7 e-mail through the Lenovo ThinkPad?                  8 A. Yes. Sometimes, yes.                  9 Q. Did you ever use the personal                  10 e-mail for business?                  11 A. I don't think so. There may be                  12 very -- maybe, you know, very few occasions,                  13 right, one or twice, somehow, you know, some                  14 of the e-mail, you know, may just get crossed                  15 over.                  16 You know, because sometimes                  17 when you type, you know, you know, the e-mail                  18 address, you know, you know, some of these                  19 will automatically show up, because my                  20 personal e-mail address has some parts of the                  21 e-mail address similar to my company e-mail                  22 address; for example, like the words "Min                  23 Li."                  24 Q. You're saying somebody could</p>	<p style="text-align: right;">Page 45</p> <p>1 A. No.                  2 Q. Do you know if either of your                  3 computers was taken into the control of                  4 either IT or your lawyers to be searched in                  5 order to pull off documents in connection                  6 with this litigation?                  7 A. My Microsoft ProBook, yes, was                  8 taken into, yeah, that purpose, yes.                  9 Q. When?                  10 A. They have gone through, yeah,                  11 my personal ProBook, yes.                  12 Q. When?                  13 A. I think sometime last year.                  14 Again, you know, I have so many things                  15 ongoing, you know, I don't remember exactly.                  16 Yeah. It should be sometime last year.                  17 Q. Sometime in 2020?                  18 A. It looks like. But again, you                  19 know, like I said, I need to, you know, find                  20 out. If you really wanted that exactly date,                  21 I think -- you know, or exactly period, I can                  22 find out for you.                  23 Q. Well, I want your best                  24 recollection right now. We may request that</p>



<p style="text-align: right;">Page 46</p> <p>1 also. But what's your best recollection,                  2 that your computer was taken in order to take                  3 documents off it for this litigation in 2020?                  4 A. Yeah, I think it should be                  5 sometime last year.                  6 Q. Who was it that did that? Who                  7 approached you?                  8 A. Who approached me.                  9 Again, this whole activity from                  10 Huahai or ZHP's perspective, it was                  11 coordinated, again, by Maggie Kong.                  12 Q. So if Maggie Kong keeps good                  13 records, she probably knows when everybody                  14 was first told about their depositions and                  15 when people were told to bring their                  16 computers in to be swept?                  17 MR. GALLAGHER: Sorry. I'm                  18 going to object to the extent you're                  19 asking for information that would                  20 constitute attorney/client privileged                  21 information.                  22 MR. SLATER: How would that be                  23 privileged? I'm asking this witness                  24 about another person he works with,</p>	<p style="text-align: right;">Page 48</p> <p>1 terms of your personal e-mail, what do you                  2 have, a Yahoo and a Hotmail address? You use                  3 both of those?                  4 A. I just have a Yahoo as my, you                  5 know, active, you know, you know, e-mail.                  6 I mean, you know, you know,                  7 from years ago may have some other, you know,                  8 but those, you know, essentially they are                  9 that e-mail, I mean, right? Like many years                  10 ago I may have like an AT&amp;T, you know,                  11 e-mail, but only -- I would say only, you                  12 know, live personal e-mail is my Yahoo                  13 e-mail.                  14 Q. And that would be                  15 minli88@yahoo.com?                  16 A. Yes.                  17 Q. From 2014 to now, is that the                  18 only e-mail address that you've used for your                  19 personal e-mail?                  20 A. Yes.                  21 Q. Do you also have a smartphone                  22 of some type that you use for work?                  23 A. I have my personal phone.                  24 Q. What type of phone is that?</p>
<p style="text-align: right;">Page 47</p> <p>1 who is not a lawyer.                  2 MR. GALLAGHER: To the extent                  3 there was attorney/client privileged                  4 information in those discussions, I                  5 caution him not to disclose that.                  6 BY MR. SLATER:                  7 Q. Did you ever use your personal                  8 e-mail to talk to anybody -- well, rephrase.                  9 Do you know if your personal                  10 e-mail was collected -- well, rephrase.                  11 Do you know if your personal                  12 e-mail was reviewed to see if work e-mails                  13 were on your personal e-mail?                  14 A. I'm sorry, it's -- could you                  15 rephrase?                  16 Q. Sure.                  17 Do you know whether any e-mails                  18 on your personal e-mail that related to your                  19 work at ZHP were pulled off the computer and                  20 provided to us?                  21 A. I don't know, because I                  22 don't -- I don't know what being pulled off.                  23 I have no idea.                  24 Q. And just so I understand, in</p>	<p style="text-align: right;">Page 49</p> <p>1 A. It's a Huawei smartphone.                  2 Q. Can you spell that for me,                  3 please?                  4 A. Huawei, H-U-A-W-E-I. Huawei is                  5 the leading smartphone company in China.                  6 Q. How long have you had the                  7 Huawei phone?                  8 A. I have my current phone since                  9 last year.                  10 Q. What did you have before last                  11 year?                  12 A. What I had before last year, I                  13 had another Huawei, but that one had some                  14 issue, so I switched to the current one.                  15 Q. What was the issue with that                  16 phone?                  17 A. The -- it's quite a funny --                  18 the -- you know, you know, the screen pops                  19 off. It's not completely pops off, but it                  20 just -- you know, I never see something like                  21 this before. You know, you know, the screen,                  22 the center of the screen, it just swells.                  23 And it's still usable, you know, but it's                  24 just -- it feels like it can broke down any</p>



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1 time, so, yeah, so I just switched to another  
 2 one. Yeah.  
 3 Q. How long did you have that  
 4 phone for, the swelling phone?  
 5 A. The swelling phone, maybe two,  
 6 three years.  
 7 Q. What did you have before that?  
 8 A. Before that I had a Samsung  
 9 smartphone.  
 10 Q. Was the Samsung phone the one  
 11 you were using as of 2014 when you joined  
 12 ZHP?  
 13 A. That was, yes.  
 14 Q. What happened to the Samsung  
 15 phone?  
 16 A. That phone was -- initially it  
 17 had some battery problem, you know,  
 18 essentially it was very difficult or even  
 19 sometimes even impossible to charge.  
 20 Sometimes, you know, when the  
 21 battery completely dead and you may be able  
 22 to recharge a little bit, but then eventually  
 23 to the point it become completely, you know,  
 24 you know, you cannot charge, so it's just

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1 dead.  
 2 Q. Did you ever have a different  
 3 phone that you used in the United States  
 4 versus the phone you used in China?  
 5 A. I have a phone that I use,  
 6 yeah, in the US.  
 7 Q. Which phone is that?  
 8 A. It's another Samsung.  
 9 Q. That's the phone you have  
 10 currently?  
 11 A. Currently I have two phones.  
 12 One, you know, you know, I mostly for, you  
 13 know, for the phone calls, you know, or  
 14 sometimes for the phone messages, you know,  
 15 receiving from the United States.  
 16 And, you know, you know, for  
 17 everything else, you know, that I use my  
 18 China-based phone, because that's the best --  
 19 that's the best way, you know, you have to  
 20 deal with.  
 21 Q. So the Samsung phone you  
 22 currently have that you use for phone calls  
 23 and phone messages, how long have you had  
 24 that phone?

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1 A. How long I get that phone.  
 2 That's a good question.  
 3 That should be -- let's see. I  
 4 would say probably end of 2013, something  
 5 like that.  
 6 Q. So the Samsung phone that you  
 7 have for your phone calls and phone messages  
 8 you had when you joined ZHP?  
 9 A. But at the same time I, you  
 10 know, I bought, you know, the other -- well,  
 11 actually, let's see.  
 12 I used another Samsung phone,  
 13 you know, you know, turned that into, you  
 14 know, you know -- yeah, I don't remember, you  
 15 know, the other Samsung phone that I  
 16 either -- that I bought in China or that I  
 17 bought in the US.  
 18 But anyhow, you know, I was  
 19 having two Samsung phones, okay. One is, as  
 20 I said, that I still use today, but mostly  
 21 for phone calls or messages to/from United  
 22 States, okay.  
 23 The other phone, as I said, I  
 24 don't remember either that I bought it in the

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1 US or bought it in China. But I used the  
 2 other one -- you know, during, you know, the  
 3 period that I joined ZHP, I used the other  
 4 one as my personal phone in China.  
 5 Q. The Samsung phone that you  
 6 currently have, am I correct that that was  
 7 the phone that you were using back when you  
 8 joined ZHP in 2014, the Samsung phone?  
 9 A. That phone was also -- yeah,  
 10 that phone was also there, yeah. I mean,  
 11 that phone, fortunately, is still working.  
 12 Maybe -- you know, maybe I -- you know, you  
 13 know, maybe the reason it's still working is  
 14 that I didn't use that much, you know what  
 15 I'm saying? It's only for, you know, you  
 16 know, for checking, you know, sometimes for  
 17 checking the phone messages, you know,  
 18 sending, you know, you know, phone messages.  
 19 Q. How about sending text messages  
 20 and receiving text messages?  
 21 A. Oh, yeah, yeah. When I say in  
 22 sending phone messages, what I mean is  
 23 actually mostly for sending text messages.  
 24 Q. And those text messages would

<p style="text-align: right;">Page 54</p> <p>1 relate to work and for personal?</p> <p>2 A. No, no. Mostly personally.</p> <p>3 Q. Did you ever send text messages</p> <p>4 on your Samsung phone that you still have</p> <p>5 related to work?</p> <p>6 A. No.</p> <p>7 Q. Not once?</p> <p>8 A. No.</p> <p>9 Q. Did you ever send text messages</p> <p>10 on any other phone related to work?</p> <p>11 A. No. I don't like, you know,</p> <p>12 text messages.</p> <p>13 Q. Well, you had three different</p> <p>14 phones for work purposes. Did you ever send</p> <p>15 text messages related to work on any of those</p> <p>16 three phones?</p> <p>17 A. No.</p> <p>18 Q. Do you know if those phones, if</p> <p>19 any of your -- rephrase.</p> <p>20 Do you know if any of your</p> <p>21 phones were taken by your company so that the</p> <p>22 information on the phones could be downloaded</p> <p>23 and then reviewed for production to us as</p> <p>24 part of the litigation? Did they take your</p>	<p style="text-align: right;">Page 56</p> <p>1 A. How long. For quite long.</p> <p>2 Q. Do you use WeChat for work</p> <p>3 purposes?</p> <p>4 A. No.</p> <p>5 Q. Never?</p> <p>6 A. Never. I mean, if you --</p> <p>7 sometimes, you know, we use WeChat to do</p> <p>8 the -- sort of like, you know, like phone</p> <p>9 conversations. I don't know if you consider</p> <p>10 that's, you know, you know, for work</p> <p>11 purposes. You know, that will be, you know,</p> <p>12 the only, you know, only way.</p> <p>13 MR. SLATER: Cheryll, you can</p> <p>14 take down the dep notice. That's</p> <p>15 fine.</p> <p>16 Q. I don't understand,</p> <p>17 respectfully, what you just said, so I'll ask</p> <p>18 it again.</p> <p>19 Have you ever used WeChat for</p> <p>20 purposes of your work for ZHP?</p> <p>21 A. As I said, you know, sometimes</p> <p>22 we use WeChat sort of like as a -- you know,</p> <p>23 use that as a phone function.</p> <p>24 Q. Okay.</p>
<p style="text-align: right;">Page 55</p> <p>1 phone or phones?</p> <p>2 A. Did they take my phones. I</p> <p>3 don't think so. I don't remember. I don't</p> <p>4 remember if they did that.</p> <p>5 Q. Did anybody ever tell you at</p> <p>6 any point that you needed to save your</p> <p>7 documents and information and not delete</p> <p>8 anything because of this litigation?</p> <p>9 A. Oh, yes, mm-hmm.</p> <p>10 Q. When was that?</p> <p>11 A. The very first time, it must be</p> <p>12 two, three years ago, I think.</p> <p>13 Q. How did you --</p> <p>14 A. But again --</p> <p>15 Q. Was it someone who spoke to</p> <p>16 you, or did you get something in writing?</p> <p>17 A. Somebody sending through the</p> <p>18 e-mail. Yeah, I think it should be someone,</p> <p>19 you know, of, you know, Maggie Kong's staff,</p> <p>20 you know, one of her staff.</p> <p>21 Q. Do you ever use WeChat?</p> <p>22 A. Yes.</p> <p>23 Q. How long have you been using</p> <p>24 WeChat?</p>	<p style="text-align: right;">Page 57</p> <p>1 A. So if you consider that that's,</p> <p>2 you know, you know, as work related, that</p> <p>3 would be the only -- you know, only occasion.</p> <p>4 Q. How often does that happen? Do</p> <p>5 you do that all the time or --</p> <p>6 A. It happens -- I wouldn't say</p> <p>7 all the times, but it happens from time to</p> <p>8 time, yeah. Because, you know, you know,</p> <p>9 sometimes, you know, you know, the other, you</p> <p>10 know, colleague, maybe they're not</p> <p>11 accessible, only through the WIFI, you know.</p> <p>12 So during that circumstances, you know,</p> <p>13 WeChat, you know, may be, you know, the most</p> <p>14 effective way, you know, just to talk to</p> <p>15 them.</p> <p>16 Q. Do you ever use the</p> <p>17 videoconferencing WeChat as part of your</p> <p>18 work?</p> <p>19 A. No.</p> <p>20 Q. You never have?</p> <p>21 A. Never. I don't like the video</p> <p>22 function.</p> <p>23 Q. Do you use videoconferencing in</p> <p>24 any other mode or from any other application</p>

<p style="text-align: right;">Page 58</p> <p>1 for your work?</p> <p>2 A. For other. I don't -- usually</p> <p>3 we just have teleconference, yeah, because,</p> <p>4 you know, using video function, it takes a</p> <p>5 lot of memory, you know, slow down the</p> <p>6 effectiveness of the communications.</p> <p>7 Q. My question is this. Have you</p> <p>8 used videoconferencing as part of your work?</p> <p>9 A. As I said, I don't recall it.</p> <p>10 You know, we -- as I said, we usually just,</p> <p>11 you know, do the audio conference.</p> <p>12 Q. You said usually you do. Does</p> <p>13 that mean sometimes you do videoconference?</p> <p>14 A. Well, because I don't remember,</p> <p>15 you know what I'm saying? There may be</p> <p>16 some -- maybe there's one time, you know,</p> <p>17 someone insisted for whatever the reason.</p> <p>18 But I just don't recall, okay?</p> <p>19 Q. Do you share documents over</p> <p>20 WeChat?</p> <p>21 A. No.</p> <p>22 Q. Have you ever for work?</p> <p>23 A. No, not for work. At least for</p> <p>24 me.</p>	<p style="text-align: right;">Page 60</p> <p>1 Exhibit 292. Is that your current resume,</p> <p>2 CV?</p> <p>3 A. Yeah, mm-hmm.</p> <p>4 Q. Is it accurate?</p> <p>5 A. Yeah, it is accurate.</p> <p>6 Q. I want to ask you a little bit</p> <p>7 about your work before you joined ZHP.</p> <p>8 According to the document, you</p> <p>9 were employed by Merck &amp; Company before you</p> <p>10 joined ZHP, is that correct?</p> <p>11 A. Mm-hmm, yes.</p> <p>12 Q. What was the work did you at</p> <p>13 Merck?</p> <p>14 A. As I described, you know, I</p> <p>15 think, quite clearly in my summary -- yeah,</p> <p>16 can you go down a little bit? -- everything</p> <p>17 basically is pretty much in there.</p> <p>18 MR. SLATER: Go all the way</p> <p>19 down, please.</p> <p>20 A. I actually worked, you know,</p> <p>21 you know, for Merck twice, right, first</p> <p>22 starting from 1998 through 2005, and then</p> <p>23 2005 to -- you know, I switched to</p> <p>24 Schering-Plough. And by the end of 2009,</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. Do you know if your</p> <p>2 conversations on WeChat have been recorded?</p> <p>3 A. I don't know. I mean, like, I</p> <p>4 don't notice there's any recording function</p> <p>5 imbedded, like, in WeChat.</p> <p>6 As far as I know, you know, I</p> <p>7 never recorded any conversations, you know,</p> <p>8 but from the other side, whether they record</p> <p>9 or not, I have no idea.</p> <p>10 Q. So you wouldn't, for example,</p> <p>11 be posting documents on WeChat? Coming back</p> <p>12 to that again. I just want to be clear.</p> <p>13 Let me ask it more clearly.</p> <p>14 Have you ever posted documents or shared</p> <p>15 documents on WeChat?</p> <p>16 A. No.</p> <p>17 MR. SLATER: Let's go to the</p> <p>18 Exhibit 292, I guess it will be, the</p> <p>19 resume, please.</p> <p>20 (Whereupon, Exhibit Number</p> <p>21 ZHP-292 was marked for</p> <p>22 identification.)</p> <p>23 BY MR. SLATER:</p> <p>24 Q. So on the screen is</p>	<p style="text-align: right;">Page 61</p> <p>1 Schering-Plough was acquired by Merck, so</p> <p>2 essentially, or effectively, I went back to</p> <p>3 Merck.</p> <p>4 Could you enlarge, you know,</p> <p>5 the text a little bit? Yeah.</p> <p>6 Yeah, basically, you know, you</p> <p>7 know, I -- when I was at Merck or</p> <p>8 Schering-Plough or after, you know, after the</p> <p>9 merger, I have a group of scientists that,</p> <p>10 you know -- you know, working in my teams.</p> <p>11 We, you know, pretty much as I</p> <p>12 said, you know, do the atypical --</p> <p>13 manufacturing atypical and all of the</p> <p>14 scientific investigations, analytical method</p> <p>15 development, validation, manufacturing</p> <p>16 process, you know, improvement.</p> <p>17 And, you know, the main focus</p> <p>18 was to do the drug degradation mechanism</p> <p>19 studies and also elucidation of the</p> <p>20 structures of drug degradation products,</p> <p>21 utilizing various LC-MS.</p> <p>22 As I listed here Thermo</p> <p>23 LTQ/Orbitrap, you know, Waters MALDI-TOF, and</p> <p>24 Waters Q-Tof, you know, these are all the</p>

<p style="text-align: right;">Page 62</p> <p>1 different, you know, types of, you know, LC,                  2 you know, liquid chromatography, mass                  3 spectrometry instrument utilized for, you                  4 know, impurity, structure elucidation                  5 purposes.                  6 Q. Did you ever --                  7 A. I -- I'm sorry, go ahead.                  8 Q. Did you ever -- rephrase.                  9 Did you ever have any                  10 involvement with Merck's losartan                  11 formulations?                  12 A. No.                  13 Q. You mentioned -- well,                  14 rephrase. I want to ask you about a few                  15 things in your resume, some of the                  16 terminology.                  17 One of things you say about                  18 your time at Merck is that your laboratory                  19 was "very well equipped with state-of-the-art                  20 analytical instruments including 9 mass                  21 spectrometers of different capabilities."                  22 A. Right.                  23 Q. During what time period did you                  24 have that state-of-the-art --</p>	<p style="text-align: right;">Page 64</p> <p>1 So essentially, you know, a                  2 drug molecule at the time, it will, you know,                  3 disintegrate, you know, become somebody else.                  4 So we need to identify, you know, those                  5 unknown impurities and, you know, to know,                  6 you know, what they are, and in order to                  7 better control them or to understand how they                  8 would form, why, you know, they would form.                  9 Q. Would these studies be                  10 performed as part of a risk assessment before                  11 the manufacturing process or during the                  12 manufacturing process?                  13 A. No, no. Actually, when I was                  14 at the Merck, also at Schering-Plough, my                  15 team was supporting commercialized products,                  16 okay?                  17 So all of the events, they                  18 happened many years after these products were                  19 launched. Even for the commercial product                  20 they were on the market for 30, 40 years.                  21 Over time was the improvement                  22 of analytical methods and also the                  23 improvement of the -- you know, the                  24 sensitivity of the methods, new impurity, you</p>
<p style="text-align: right;">Page 63</p> <p>1 A. That was mostly study from                  2 2005, and that was the time that I joined                  3 Schering-Plough.                  4 So since my joining, I start                  5 to, you know, establish and also was                  6 expanding my, you know, my team.                  7 So eventually, I think two to                  8 three years into that time, like I would say                  9 around, you know, maybe 2008, I have these                  10 full set of, you know, equipments.                  11 Yeah, I would say, yeah,                  12 because 2009 we already -- end of 2009 we                  13 already acquired by Merck. Yeah, so it's                  14 somewhere around 2008, the instrument                  15 capability of my team reached to -- you know,                  16 essentially to, you know, to a peak.                  17 Q. You mentioned drug degradation                  18 studies. What is a drug degradation study?                  19 A. Well, anything well decomposed                  20 over time, you know, it's -- the difference                  21 is just, you know, to the extent. Some are                  22 very stable, but still they may decompose,                  23 you know, a little bit. Some will decompose                  24 more obviously than the others, right?</p>	<p style="text-align: right;">Page 65</p> <p>1 know, will emerge or will -- you know, they                  2 actually sometimes, in some, you know, cases,                  3 you know, those impurities, they've always                  4 been there; it's just because, you know, the                  5 old methodology was not sensitive or specific                  6 enough. You know, they were just there, you                  7 know, undetected.                  8 But then one day, you know,                  9 sometimes by a rather, you know,                  10 coincidental, you know, you know, factors,                  11 you know, they become known. So, yeah, so                  12 then my team quite often will be called in to                  13 do the investigation.                  14 Q. Do you recall any specific                  15 examples of those decomposing chemicals that                  16 Merck had found, where it had been happening                  17 for a long time and your company didn't know                  18 it?                  19 A. Oh, yeah. Oh, yeah. I can                  20 give you one example. For that example we                  21 also published a paper, actually. Yeah.                  22 So there was one product, it                  23 containing a, you know, drug substance, or                  24 also we can call it active pharmaceutical</p>



<p>Page 66</p> <p>1 ingredients.</p> <p>2 You know, that API was</p> <p>3 betamethasone dipropionate, okay, which is a</p> <p>4 steroids, you know, anti-inflammatory, you</p> <p>5 know, you know, steroids. It's a lotion</p> <p>6 product, okay, as far as I can remember.</p> <p>7 And the reason that I can</p> <p>8 remember is because that was the -- that was</p> <p>9 the first, you know, significant</p> <p>10 investigation my team was working on, right?</p> <p>11 So there was, you know, a known</p> <p>12 degradation product, okay? So that</p> <p>13 degradation product was a hydrolytic, you</p> <p>14 know, degradation product. It's called</p> <p>15 21-monopropionate of betamethasone.</p> <p>16 And at this degradation</p> <p>17 product -- I'm sorry.</p> <p>18 This degradation product has</p> <p>19 always been known. You know, they eluted at</p> <p>20 one particular place, right? And then all of</p> <p>21 a sudden there was one day in the QC lab, it</p> <p>22 just happened to be maybe that one particular</p> <p>23 column has slightly better resolution than</p> <p>24 the others, right, and that peak is splitted</p> <p>Page 67</p> <p>1 into two peaks, okay? It just barely, you</p> <p>2 know, you know, split it, right?</p> <p>3 And according to the SOP of the</p> <p>4 QC lab, once you have the splitting on a --</p> <p>5 you know, you know, on a particular peak,</p> <p>6 right, you have to do investigation, right?</p> <p>7 Because according to the SOP, you have to do</p> <p>8 what we call a drop line integration, right?</p> <p>9 So basically, then, the major</p> <p>10 one is still this monoester, which is a known</p> <p>11 degradant, but the other one become an</p> <p>12 unknown peak, right?</p> <p>13 So then my, you know, my group</p> <p>14 did a comprehensive, you know, investigation</p> <p>15 using LC-MS and also utilizing NMR, and so</p> <p>16 finally we were able to find, you know,</p> <p>17 another degradant that has been unknown for</p> <p>18 this particular, you know, you know, drug</p> <p>19 substances.</p> <p>20 And betamethasone dipropionate</p> <p>21 at the time, I think around maybe 2007 we did</p> <p>22 the investigation at, you know,</p> <p>23 Schering-Plough at the time, that product was</p> <p>24 already, I was told, on the market for like</p>	<p>Page 68</p> <p>1 20, 30 years already.</p> <p>2 So based upon the structure</p> <p>3 that we determined, then we start to search</p> <p>4 the literature, right? And then based upon</p> <p>5 the literature, you know, you know, this</p> <p>6 particular degradant, you know -- basically</p> <p>7 historical, you know, literature provided</p> <p>8 some clue as to how, you know, this</p> <p>9 degradation could come, right, or, you know,</p> <p>10 could happen.</p> <p>11 But based upon, you know, you</p> <p>12 know, larger reasoning, we figured that</p> <p>13 this -- you know, the literature results</p> <p>14 cannot completely explain, you know, you</p> <p>15 know, the phenomenon that we see.</p> <p>16 So based upon that and also,</p> <p>17 you know, and also based upon the stability</p> <p>18 results, we finally able to -- you know, to</p> <p>19 find out a new or a novel degradation</p> <p>20 mechanism from betamethasone dipropionate.</p> <p>21 So we also, you know,</p> <p>22 provide -- actually published another paper</p> <p>23 specifically describing the -- you know, you</p> <p>24 know, this newly formed, you know,</p> <p>Page 69</p> <p>1 degradation mechanism, you know, even for a</p> <p>2 product that has been on the market for</p> <p>3 nearly 30 years.</p> <p>4 There will still be, as I said,</p> <p>5 even with the progress, you know, of the</p> <p>6 technology, you know, better, you know,</p> <p>7 sensitivity, better, you know, specificity.</p> <p>8 You know, we're able to, you know, to find</p> <p>9 out, and also we're able to resolve those</p> <p>10 issues.</p> <p>11 So after that --</p> <p>12 Q. I'm sorry to interrupt. All I</p> <p>13 asked is if you recall any instances. I</p> <p>14 didn't ask you for the full story.</p> <p>15 A. Okay. All right. Okay, sorry.</p> <p>16 Yeah, I thought you...</p> <p>17 MR. GALLAGHER: Adam, we've</p> <p>18 been going about an hour and ten</p> <p>19 minutes. You can ask a few more</p> <p>20 questions, but maybe at some point we</p> <p>21 can take a break.</p> <p>22 MR. SLATER: Whatever you want</p> <p>23 to do.</p> <p>24 ///</p>
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<p style="text-align: right;">Page 70</p> <p>1 BY MR. SLATER:</p> <p>2 Q. I'm looking at your -- let's go</p> <p>3 to the first page, now, of the resume.</p> <p>4 A. Sure.</p> <p>5 So maybe after the resume</p> <p>6 question, we can take a break?</p> <p>7 MR. SLATER: Why don't you go</p> <p>8 take the break now.</p> <p>9 THE WITNESS: Okay. So we have</p> <p>10 what, 10, 15 minutes or what?</p> <p>11 MR. SLATER: Let's go off the</p> <p>12 record, please.</p> <p>13 THE VIDEOGRAPHER: The time</p> <p>14 right now is 8:12 a.m. We're now off</p> <p>15 the record.</p> <p>16 (Whereupon, a recess was</p> <p>17 taken.)</p> <p>18 THE VIDEOGRAPHER: The time</p> <p>19 right now is 8:27 a.m. We're back on</p> <p>20 the record.</p> <p>21 (Whereupon, Exhibit Number</p> <p>22 ZHP-293 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 72</p> <p>1 the most challenging, you know, issues, as I</p> <p>2 put there, yeah, the most challenging</p> <p>3 technical issues.</p> <p>4 Q. When I ask what CEMAT is, is it</p> <p>5 a laboratory or a separate office, or is</p> <p>6 it -- let me ask this question.</p> <p>7 In terms of what CEMAT is, is</p> <p>8 it part of ZHP?</p> <p>9 A. Yes.</p> <p>10 Q. Where is it located?</p> <p>11 A. It's located in headquarter of</p> <p>12 ZHP, E Linghai, Zhejiang Province, China.</p> <p>13 Q. Which facility?</p> <p>14 A. Which facility. It's in</p> <p>15 Xunqiao facility, yeah, Xunqiao site.</p> <p>16 Q. Why was it necessary for you to</p> <p>17 establish CEMAT?</p> <p>18 A. Why it's necessary?</p> <p>19 Q. Let me ask the question very</p> <p>20 specifically.</p> <p>21 What was the specific need --</p> <p>22 well, rephrase.</p> <p>23 What was the specific reason</p> <p>24 why CEMAT was established?</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. On the screen is Exhibit 293.</p> <p>2 Do you recognize that document?</p> <p>3 A. Oh, yeah.</p> <p>4 Q. What is it?</p> <p>5 A. Right now it's just, you know,</p> <p>6 the starting of the summary of my LinkedIn</p> <p>7 page.</p> <p>8 MR. SLATER: All right.</p> <p>9 Cheryll, can you scroll down to where</p> <p>10 it talks about -- right there.</p> <p>11 Perfect. No. A little more up. Yes,</p> <p>12 perfect.</p> <p>13 Q. Your LinkedIn page says that</p> <p>14 you established something called CEMAT,</p> <p>15 C-E-M-A-T.</p> <p>16 A. Yes, CEMAT.</p> <p>17 Q. What is that?</p> <p>18 A. Basically, it's just like --</p> <p>19 you know, in the sense that I rebuilt my, you</p> <p>20 know, research team at Huahai.</p> <p>21 You know, the mission is pretty</p> <p>22 much the same, you know, you know, in terms</p> <p>23 of, you know, supporting those issues related</p> <p>24 to pharmaceutical impurities, and those are</p>	<p style="text-align: right;">Page 73</p> <p>1 A. Well, basically to improve, you</p> <p>2 know, the company's, you know, capability,</p> <p>3 you know, in this particular field.</p> <p>4 Q. And that field would include</p> <p>5 the identification of impurities in drug</p> <p>6 products?</p> <p>7 MR. GALLAGHER: Objection.</p> <p>8 Vague.</p> <p>9 THE WITNESS: I'm sorry.</p> <p>10 MR. GALLAGHER: You can answer.</p> <p>11 THE WITNESS: Okay.</p> <p>12 Yes, drug products as well as</p> <p>13 new drug substances.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Is API a drug substance?</p> <p>16 A. Yeah. API, yeah, is another</p> <p>17 name usually for drug substance, yes.</p> <p>18 Q. When I said "drug products,"</p> <p>19 you were thinking finished dose?</p> <p>20 A. Yes. That's usually people,</p> <p>21 you know, call it, yes.</p> <p>22 Q. The identification of</p> <p>23 impurities in drug substances is an important</p> <p>24 part of cGMP, correct?</p>



<p style="text-align: right;">Page 74</p> <p>1 MR. GALLAGHER: Objection.                  2 Vague.                  3 You can answer.                  4 THE WITNESS: Okay.                  5 A. Identification is -- yes, it's                  6 part of the cGMP requirements, yes.                  7 MR. SLATER: Cheryll, let's put                  8 up the next exhibit, this PowerPoint                  9 that we have regarding CEMAT, just to                  10 identify it for a moment. I believe                  11 it's ZHP00404315 to 327.                  12 (Whereupon, Exhibit Number                  13 ZHP-294 was marked for                  14 identification.)                  15 A. The exhibit is gone? Okay.                  16 BY MR. SLATER:                  17 Q. Do you see the PowerPoint we've                  18 put on the screen?                  19 A. Yeah, sure.                  20 Q. Did you create that PowerPoint?                  21 A. My associates probably prepared                  22 a draft and then I finalized it, yes.                  23 Q. What was the purpose of                  24 creating this PowerPoint?</p>	<p style="text-align: right;">Page 76</p> <p>1 Process impurities would                  2 include, for example, the NDMA created                  3 by the zinc chloride process; that's a                  4 process impurity, correct?                  5 A. Retrospectively, yes.                  6 Q. And the creation of NDMA and                  7 NDEA in the TEA process with sodium nitrite                  8 quenching, those would be process impurities,                  9 correct?                  10 A. Right.                  11 Q. And in both those -- rephrase.                  12 After both those manufacturing                  13 processes -- well, rephrase.                  14 For the zinc chloride process,                  15 the root cause of the creation of NDMA was                  16 that the dimethylformamide was decomposing to                  17 create dimethylamine, which then reacted                  18 during the process with nitrous acid to                  19 create NDMA, correct?                  20 MR. GALLAGHER: Objection.                  21 Vague, and foundation.                  22 BY MR. SLATER:                  23 Q. That's the root cause, correct?                  24 A. Yeah, that's the root cause</p>
<p style="text-align: right;">Page 75</p> <p>1 A. Well, there's multiple                  2 purposes. You know, one, just to present to,                  3 you know, our colleagues, you know, and                  4 sometimes, you know, present to, you know, to                  5 my boss, you know, during the, like,                  6 quarterly meetings, you know, particularly in                  7 the early days.                  8 You know, you need to, you                  9 know, you need to show, you know, right, what                  10 you can achieve.                  11 MR. SLATER: I'm sorry. Let's                  12 go to the page after the cover page,                  13 please? Perfect.                  14 Q. Looking at the Mission of                  15 CEMAT, it says, "To solve the most                  16 challenging technical problems encountered                  17 from research and development to scale up and                  18 manufacture of drug substances and finished                  19 products, particularly those related to                  20 process impurities, degradation products, and                  21 solid state and polymorphism."                  22 Do you see that?                  23 A. Mm-hmm, sure.                  24 Q. When this -- rephrase.</p>	<p style="text-align: right;">Page 77</p> <p>1 retrospectively after, you know, the events                  2 occurred and we did quite a, you know,                  3 retrospective analysis, yes.                  4 Q. And that retrospective analysis                  5 occurred when?                  6 A. After the June 6th -- you know,                  7 when the events was first came out.                  8 Q. Going to the TEA process with                  9 sodium nitrite quenching, the root cause for                  10 the NDMA and NDEA was that triethylamine                  11 hydrochlorothiazide was used as a catalyst.                  12 That substance then would give off or produce                  13 diethylamine or dimethylamine, and one or the                  14 other or both would then react with nitrous                  15 acid to create NDEA and NDMA.                  16 That's the root cause in that                  17 manufacturing process, correct?                  18 MR. GALLAGHER: Objection.                  19 Vague, foundation, and compound.                  20 You can answer.                  21 A. Okay. The root cause, I think                  22 actually, based upon my understanding, they                  23 are slightly different.                  24 The -- you know, the reason</p>

<p>Page 78</p> <p>1 that I'm saying that is, you know, based upon</p> <p>2 all of the new knowledge, right, that</p> <p>3 accumulated by the industry, as well as, you</p> <p>4 know, from the regulators, okay?</p> <p>5 For the formation for the TEA</p> <p>6 process, for the formation of the TEA,</p> <p>7 basically you have two mechanisms. One is</p> <p>8 the DEA is a typical process impurity of TEA,</p> <p>9 so DEA would also, yeah, would react with the</p> <p>10 nitrous acid to perform NDEA.</p> <p>11 But also, according to, as I</p> <p>12 said, again, updated, you know, you know,</p> <p>13 information, the triethylamine could also</p> <p>14 react with nitrous acid, but the efficiency</p> <p>15 is not as high as the reaction with the TEA,</p> <p>16 right?</p> <p>17 So -- yeah, so basically, you</p> <p>18 know, that's the mechanism for that process,</p> <p>19 okay, or the root cause.</p> <p>20 And for NDMA, for its presence</p> <p>21 in the TEA process, and I think the root</p> <p>22 cause is the -- in some of the TEA raw</p> <p>23 material it may contain a trace amount of,</p> <p>24 you know, of dimethylamine, okay, so that's</p>	<p>Page 80</p> <p>1 A. It was during, you know, again,</p> <p>2 part of the retrospective, you know,</p> <p>3 investigations.</p> <p>4 And also those knowledge, you</p> <p>5 know, was not gained instantaneously. And</p> <p>6 obviously, you know -- I mean, it's like if</p> <p>7 you look at some of the FDA's -- their</p> <p>8 training material, FDA's announcement, you</p> <p>9 know, you know, this whole thing is very</p> <p>10 complicated, you know, so it takes time and</p> <p>11 great efforts, right?</p> <p>12 So you will first, you know,</p> <p>13 reveal the most obvious, and then eventually,</p> <p>14 you know, when time goes by, you know. And</p> <p>15 so some of the other minor contributing</p> <p>16 factors was also being, you know, discovered.</p> <p>17 Q. Before June of 2018, did ZHP</p> <p>18 ever have any information indicating that any</p> <p>19 of the valsartan manufacturing processes</p> <p>20 could cause any nitrosamine to be created?</p> <p>21 A. No. The whole industry, as</p> <p>22 well as the regulator, did not have that</p> <p>23 knowledge, including ZHP.</p> <p>24 Q. And I've seen some vocabulary</p>
<p>Page 79</p> <p>1 one root cause.</p> <p>2 I think that there's another</p> <p>3 root cause for the presence of NDMA in the</p> <p>4 TEA process, which is from, you know, for --</p> <p>5 as far as I remember, for very limited, you</p> <p>6 know, batch numbers. Because for some of</p> <p>7 the, you know, product, they were</p> <p>8 manufactured, you know, using the share line,</p> <p>9 you know, with the zinc chloride valsartan.</p> <p>10 And I think, you know, so for those limited</p> <p>11 number of batches, that's another root cause.</p> <p>12 So I think that's pretty much,</p> <p>13 you know, yeah, the root cause, you know, you</p> <p>14 know, for the TEA process for NDMA and NDEA.</p> <p>15 Q. When you refer to the shared</p> <p>16 production line, are you talking about</p> <p>17 cross-contamination?</p> <p>18 A. Well, that's one way, you know,</p> <p>19 from some of the inspections, you know, you</p> <p>20 know, people use that phrase, but I would</p> <p>21 say, rather, it's carryover, you know, of</p> <p>22 some of the residual impurities.</p> <p>23 Q. And when was that learned?</p> <p>24 When was that root cause figured out?</p>	<p>Page 81</p> <p>1 in some things that I've read, so I just want</p> <p>2 to make sure we're on the same page as to</p> <p>3 what certain things mean as we go forward if</p> <p>4 we could, please.</p> <p>5 A. No problem.</p> <p>6 Q. So I've seen the term</p> <p>7 "nitrosamine" and I've seen the term "nitroso</p> <p>8 compound" or "N-nitroso compound."</p> <p>9 Does that all basically mean</p> <p>10 the same thing?</p> <p>11 A. No. To be scientifically</p> <p>12 precise, they are not the same.</p> <p>13 Nitroso compound is a very --</p> <p>14 you know, I'm a scientist, okay, right? If</p> <p>15 somebody just tell me nitroso compound, you</p> <p>16 know, you know, any compound have a nitroso</p> <p>17 group, they're called a nitroso compound. So</p> <p>18 nitrosamine is just a subtype of the nitroso</p> <p>19 compound, all right?</p> <p>20 And the same thing, you know,</p> <p>21 N-nitroso compound is also a subtype of</p> <p>22 nitroso compound, but N-nitroso compound</p> <p>23 including the nitrosamine.</p> <p>24 MR. SLATER: Cheryll, let's</p>

<p style="text-align: right;">Page 82</p> <p>1 take this document down, and go to                  2 document -- now what are we up to,                  3 294? Is the next document 294?                  4 Is the next exhibit 294?                  5 THE STENOGRAPHER: 295.                  6 MR. SLATER: 295. I'm always                  7 off by one, Maureen.                  8 (Whereupon, Exhibit Number                  9 ZHP-295 was marked for                  10 identification.)                  11 MR. SLATER: Looking at Exhibit                  12 295, let's put up ZHP00190573.                  13 BY MR. SLATER:                  14 Q. This is an e-mail dated                  15 July 27, 2017.                  16 Do you see that?                  17 A. Okay.                  18 Q. Do you see the date in the top                  19 right?                  20 A. Let's see. Yeah, uh-huh.                  21 Q. And you can see the person who                  22 wrote it up in the top left. You can see                  23 Jinsheng Lin.                  24 Do you see that?</p>	<p style="text-align: right;">Page 84</p> <p>1 MR. SLATER: The link, the                  2 hopper.                  3 (Whereupon, Exhibit Number                  4 ZHP-296 was marked for                  5 identification.)                  6 A. That will be better for most of                  7 you guys. Yeah, for me that's fine, but...                  8 MR. SLATER: Okay if I proceed?                  9 MR. GALLAGHER: Yes, please. I                  10 see it. It's up.                  11 BY MR. SLATER:                  12 Q. So it says -- rephrase.                  13 This e-mail dated by one of                  14 your key technical people, Jinsheng Lin, it                  15 says it's to multiple people. And I just --                  16 tell me if I get these names right. Jucai                  17 Ge, Tianpei Huang, Wangwei Chen, Wenquan Zhu.                  18 A. Okay.                  19 Q. Wenbin Chen.                  20 A. Uh-huh.                  21 Q. Mr. Li.                  22 A. That's me. Yeah, that's me.                  23 Q. Peng Dong?                  24 A. Wait a second. Oh, wait. I'm</p>
<p style="text-align: right;">Page 83</p> <p>1 A. Yes. He was, yeah, one of my                  2 staff, yes.                  3 Q. What was his role? What was                  4 his title?                  5 A. His title right now is                  6 technical associate director, I think.                  7 Something like that, yeah.                  8 Q. Would it have been the same                  9 title back in July of 2017?                  10 A. No. He had one -- at least one                  11 promotion. He maybe at the time was like                  12 assistant, you know, like technical director,                  13 you know, but I don't, you know, keep those                  14 things, you know, you know, you know, up and                  15 running all the time in my mind. Yeah. But                  16 he -- yeah, he is one of the key technical                  17 person in my team.                  18 MR. GALLAGHER: Adam, do you                  19 have an English language version of                  20 this document?                  21 MR. SLATER: We do. I think                  22 Cheryll can put it into that.                  23 MR. GALLAGHER: Into the link?                  24 Great.</p>	<p style="text-align: right;">Page 85</p> <p>1 still seeing the Chinese version. Are you                  2 reading the English version?                  3 Q. I'm certainly not reading the                  4 Chinese; I'm reading the English. But I'm                  5 just going through the names right now.                  6 A. Yeah, sure. Yeah, go ahead.                  7 Q. So we just -- we established                  8 you're one of the people who received this                  9 e-mail, correct?                  10 A. Oh, yes.                  11 Q. Also Peng Dong?                  12 A. Mm-hmm.                  13 Q. Lihong Lin?                  14 A. Mm-hmm.                  15 Q. Yanfeng Liu?                  16 A. Yes, that's pretty close.                  17 Q. Peng Wang?                  18 A. Penh Wang, yes.                  19 Q. And Wenling Zhang.                  20 A. Yes.                  21 Q. Okay. And it looks like the                  22 subject is "Valsartan Impurity K."                  23 Does it say that, or is that an                  24 attachment?</p>

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1 A. Yeah, "Valsartan Impurity K,"  
2 yes.  
3 Q. Okay. So the subject is  
4 "Valsartan Impurity K," correct?  
5 A. Yes, looks like, yes.  
6 Q. And this is to -- it's  
7 addressed to Ms. Ge. Is that pronounced  
8 right, G-E, Ge?  
9 A. Yeah, yeah. Yes. That's  
10 perfect almost, yes.  
11 Q. And they're talking about  
12 impurity they see in one of the production  
13 processes, correct?  
14 A. Yeah, mm-hmm.  
15 MR. SLATER: And let's turn to  
16 the second page now of the document,  
17 please, at the top.  
18 Q. Tell me if I have this pretty  
19 much correct. At the top it says, "Through  
20 the secondary mass spectrometry analysis" --  
21 and I want to stop there.  
22 What is secondary mass  
23 spectrometry analysis?  
24 A. It's basically you have --

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1 well, actually, you know, you have three  
2 stages. You're going to the -- first the  
3 mass detector, right? It's looking for the  
4 parent molecule away, or the parent most  
5 usually like protonated molecular eye.  
6 And then you're going to a  
7 collision cell, you know, you know, you know,  
8 usually with gas, either nitrogen, helium,  
9 or, you know, some other gas, and to break  
10 them apart.  
11 And then you have, you know, a  
12 number of, you know, you know, what do we  
13 call it, fragments, right? And then you go  
14 to another, you know, mass detector. Yeah.  
15 So sometimes it's also called a triple quad  
16 mass spectrometry, but sometimes just called  
17 MS2 or /MS.  
18 Q. Again starting -- rephrase.  
19 Starting at the top, it says,  
20 "Through the secondary mass spectrometry  
21 analysis, it can be inferred that the extra  
22 NO substituent is in the cyclic compound  
23 fragment, and it is very likely that it is an  
24 N-NO compound; it is similar to the

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1 N-nitrosodimethylamine that occurs in  
2 valsartan when quenched with sodium nitrite,  
3 and its structure is very toxic. Its  
4 possible formation route is shown as  
5 follows," and then we have the diagrams.  
6 Did I get that right?  
7 A. Yeah, yeah, it looks like.  
8 Q. And if we go further down below  
9 the pictures, there is the second paragraph  
10 after the pictures.  
11 MR. SLATER: You can keep  
12 scrolling down, please, Cheryll.  
13 Q. Looking now at the second  
14 paragraph under the diagrams, the e-mail  
15 says, "If it is confirmed as the above  
16 speculated structure, then its toxicity will  
17 be very strong, and there will be an  
18 extremely high GMP risk. This is a common  
19 problem in the production and synthesis of  
20 sartan APIs. It is recommended to improve  
21 other quenching processes (such as NaClO)  
22 along with the optimization of the valsartan  
23 sodium azide quenching process."  
24 Did I get that pretty much

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1 right?  
2 A. Yeah, it sounds like. Yeah.  
3 Q. And then going to the last  
4 paragraph of this e-mail you received  
5 July 27, 2017, it says, "I've also attached a  
6 patent of a 2013 sodium azide NaClO quenching  
7 method by Zhejiang Second Pharma Co.,  
8 Limited. They proposed that the use of NaNO2  
9 quenching will result in the formation of  
10 N-NO impurities. At the same time, they used  
11 ZHP's crude Valsartan in their LC-MS test and  
12 detected this impurity. This indicates that  
13 other companies have paid attention to the  
14 quality problem very early on. So leaders  
15 please pay attention to this issue."  
16 And then it's signed Jinsheng  
17 Lin, CEMAT, July 27, 2017, correct?  
18 A. Yeah, looks like, uh-huh.  
19 Q. And if we go back up to the top  
20 now, just to reiterate a couple things, it  
21 said in part that what was being seen here  
22 was similar to the NDMA that occurs in  
23 valsartan when quenched with sodium nitrite,  
24 correct? You saw that language up at the

<p style="text-align: right;">Page 90</p> <p>1 top?</p> <p>2 A. Yes.</p> <p>3 MR. GALLAGHER: Objection.</p> <p>4 Vague, and mischaracterizes the</p> <p>5 document.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. And, therefore, as of July 27,</p> <p>8 2017, you and others in your company knew</p> <p>9 that when valsartan was quenched with sodium</p> <p>10 nitrite, it was forming in NDMA, correct?</p> <p>11 MR. GALLAGHER: Objection.</p> <p>12 Again, vague and mischaracterizes the</p> <p>13 document.</p> <p>14 A. You know, you know, I have</p> <p>15 received a lot of e-mails, and it looks like</p> <p>16 my name was there. But somehow I don't know,</p> <p>17 you know -- you know, he didn't specifically</p> <p>18 follow up with me or brought that, you know,</p> <p>19 specifically to my attention.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Well, that's what the e-mail</p> <p>22 says, right?</p> <p>23 A. Right, right, I know. Yeah, I</p> <p>24 know that my name was there, but I, you know,</p>	<p style="text-align: right;">Page 92</p> <p>1 You can answer, Dr. Li.</p> <p>2 A. I'm sorry, what is the question</p> <p>3 again? Sorry.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Sure.</p> <p>6 When people outside ZHP learned</p> <p>7 that the valsartan manufacturing process was</p> <p>8 creating NDMA, that was a significant GMP</p> <p>9 problem, correct?</p> <p>10 A. Well, that's what he said, yes.</p> <p>11 Q. And he also said this is a</p> <p>12 common problem in the production and</p> <p>13 synthesis of sartan APIs. So at that point</p> <p>14 people within ZHP knew that with the</p> <p>15 manufacture of their sartan APIs,</p> <p>16 nitrosamines were being created.</p> <p>17 That's what he's referring to</p> <p>18 in this e-mail, correct?</p> <p>19 A. That, it looks like, is the</p> <p>20 case.</p> <p>21 Q. And then he says, "It is</p> <p>22 recommended to improve other quenching</p> <p>23 processes (such as NaClO)."</p> <p>24 And if you could translate that</p>
<p style="text-align: right;">Page 91</p> <p>1 receive huge amount of e-mail.</p> <p>2 Usually, you know, for</p> <p>3 something -- I told them if something, you</p> <p>4 know, you know, they feel important, they</p> <p>5 should remind me or, you know, you know,</p> <p>6 brought up, you know, to my attention.</p> <p>7 Q. And going down further to that</p> <p>8 second-to-last paragraph we read, just to</p> <p>9 reiterate and walk through, Jinsheng Lin had</p> <p>10 written, "If it is confirmed as the above</p> <p>11 speculated structure, then its toxicity will</p> <p>12 be very strong, and there will be an</p> <p>13 extremely high GMP risk."</p> <p>14 That's what he wrote, correct?</p> <p>15 A. That's what he wrote, but, you</p> <p>16 know, he's not a toxicologist, so I think</p> <p>17 that's his speculation.</p> <p>18 Q. Well, certainly with regard to</p> <p>19 NDMA in valsartan, that would be, and turned</p> <p>20 out to be, a significant GMP problem when it</p> <p>21 was discovered outside of ZHP, correct?</p> <p>22 A. Let me see. Which --</p> <p>23 MR. GALLAGHER: Objection.</p> <p>24 Calls for speculation.</p>	<p style="text-align: right;">Page 93</p> <p>1 for me, please.</p> <p>2 A. I'm sorry, which one here?</p> <p>3 Q. The NaClO. Is that sodium</p> <p>4 nitrite?</p> <p>5 A. No. That's the -- no, that's</p> <p>6 another quenching reagent. No, it's not</p> <p>7 sodium nitrite.</p> <p>8 Q. What is it?</p> <p>9 A. It's one of the</p> <p>10 chloro-containing, you know, acid. This one</p> <p>11 is actually the main ingredient in bleach.</p> <p>12 Q. Hypochlorite.</p> <p>13 A. Yeah.</p> <p>14 Q. Is that hypochlorite?</p> <p>15 A. Yeah, I think it should be that</p> <p>16 one, yes.</p> <p>17 Q. Let me ask it again then, now</p> <p>18 that I just figured it out with you.</p> <p>19 With my -- all right. Let me</p> <p>20 rephrase.</p> <p>21 He wrote, "It is recommended to</p> <p>22 improve other quenching processes, such as</p> <p>23 hypochlorite" -- that's actually bleach,</p> <p>24 right?</p>



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1 A. Yes.

2 Q. -- "along with the optimization

3 of the valsartan sodium azide quenching

4 process."

5 So he's recommending that the

6 sodium azide quenching process that you had

7 been using be optimized, be improved,

8 correct?

9 A. Looks like, yes.

10 Q. And going back to the next

11 paragraph, he actually points out that he is

12 attaching a patent, which we'll pull out in

13 just a moment, from a 2013 sodium azide

14 hypochlorite quenching method by a different

15 company, Zhejiang Second Pharma Co., Limited.

16 That's another company in

17 China, correct?

18 A. Yes.

19 Q. And, again, the NaClO, that's

20 hypochlorite, which is bleach, correct?

21 A. Yes.

22 Q. And he says that that company

23 "proposed that the use of NaNO<sub>2</sub> quenching

24 will result in the formation of N-NO

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1 impurities."

2 NaNO<sub>2</sub> is sodium nitrite,

3 correct?

4 A. NaNO<sub>2</sub>, yes.

5 Q. And N-NO impurities would be

6 nitrosamine impurities, correct?

7 A. I'm sorry, which one?

8 Q. Where it says "N-NO," those

9 would be nitrosamine impurities, correct?

10 A. I'm sorry. I don't know which

11 you're referring to.

12 MR. SLATER: Scroll down a

13 little, Cheryl. I think it's cut

14 off.

15 Q. In the last paragraph?

16 A. Oh, yeah. Yeah, it's N-NO,

17 yeah, impurity, yes. It's N-nitro impurity,

18 yes.

19 Q. And he then says, "At the same

20 time, they used ZHP's crude Valsartan in

21 their LC-MS test and detected this impurity."

22 And "LC-MS," that would be

23 liquid chromatography-mass spectrometry? Do

24 I have that right?

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1 A. Yeah, mm-hmm.

2 Q. And again, as I'm going to show

3 you in a moment, he's talking about what he

4 read in this patent by this other company in

5 China.

6 And he then says, "This

7 indicates that other companies have paid

8 attention to the quality problem very early

9 on."

10 Do you see that?

11 A. Mm-hmm.

12 Q. And this quality problem he's

13 talking about is the sodium nitrite quenching

14 leading to the creation of nitrosamines,

15 correct?

16 A. Looks like.

17 Q. And he then says, "So leaders

18 please pay attention to this issue."

19 And when he's referring to

20 "leaders," would that be the people on this

21 e-mail, including yourself and Peng Dong and

22 Lihong Lin, and the others on that e-mail?

23 MR. GALLAGHER: Objection.

24 Vague, and calls for speculation.

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1 You can answer, Dr. Li.

2 A. Yeah, it looks like at least

3 the two, yes.

4 BY MR. SLATER:

5 Q. Now let's go, if we could --

6 well, actually, let me ask you this question.

7 This e-mail -- we have

8 something called metadata, and metadata is

9 information we get when we get produced

10 documents; where they came from, who authored

11 them, etcetera. That's something we exchange

12 as part of this litigation.

13 A. Okay.

14 Q. The metadata on this said that

15 this came from a folder titled "Documents"

16 from your old computer, which apparently,

17 according to the metadata, was copied from

18 your old desktop into your new computer in or

19 about June 2018.

20 Do you remember doing that?

21 A. I'm sorry?

22 MR. GALLAGHER: Objection.

23 Objection. Vague and foundation.

24 ///



<p style="text-align: right;">Page 98</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Do you remember doing that,</p> <p>3 copying this document from one computer into</p> <p>4 another computer in or about June of 2018?</p> <p>5 A. I didn't do that.</p> <p>6 Q. So if that happened, somebody</p> <p>7 else would have done it, and that would have</p> <p>8 been stored in --</p> <p>9 A. Probably IT, yeah. As I</p> <p>10 said -- yeah.</p> <p>11 Q. So this e-mail clearly is --</p> <p>12 rephrase.</p> <p>13 So based on this e-mail, your</p> <p>14 company was -- well, let me rephrase this.</p> <p>15 Did your company ever tell the</p> <p>16 FDA or any other regulators about its</p> <p>17 knowledge about the creation of nitrosamines</p> <p>18 including NDMA from the quenching with sodium</p> <p>19 nitrite?</p> <p>20 Do you recall your company</p> <p>21 telling the FDA or any regulatory authorities</p> <p>22 about that?</p> <p>23 A. Well --</p> <p>24 MR. GALLAGHER: Objection.</p>	<p style="text-align: right;">Page 100</p> <p>1 compound with irbesartan, yeah. It's not</p> <p>2 valsartan. But based upon that, yeah, it</p> <p>3 looks like he's making -- you know, making</p> <p>4 his guess.</p> <p>5 Q. Well, he's comparing it and</p> <p>6 calling it similar to the NDMA that forms in</p> <p>7 valsartan when quenched with sodium nitrite.</p> <p>8 That's what he said, right?</p> <p>9 A. Yeah, that's -- again, you</p> <p>10 know, you know, that's his, you know, his</p> <p>11 guess or his speculation.</p> <p>12 Q. Well, he doesn't say he's</p> <p>13 guessing or speculating, does he?</p> <p>14 A. He didn't say, but basically</p> <p>15 from the context, you know, yeah. I mean,</p> <p>16 it's obvious.</p> <p>17 Q. Well, it's also obvious he said</p> <p>18 in the second-to-last paragraph, if we scroll</p> <p>19 down to it, that "If it is confirmed as the</p> <p>20 above speculated structure in this</p> <p>21 irbesartan, then its toxicity will be very</p> <p>22 strong, and there will be an extremely high</p> <p>23 GMP risk."</p> <p>24 Meaning if it's a nitrosamine,</p>
<p style="text-align: right;">Page 99</p> <p>1 Vague.</p> <p>2 A. In this particular case, you</p> <p>3 know, he's talking -- well, that particular</p> <p>4 case with, you know, irbesartan, right? And</p> <p>5 so he's, you know, you know, you know, making</p> <p>6 a kind of a, you know, you know, guess.</p> <p>7 You know, I mean, all of the</p> <p>8 language that you can see, you know, you</p> <p>9 know, yeah, because the reaction, you know,</p> <p>10 that he showed is irbesartans, yeah.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Well, if we go to the top of</p> <p>13 this page --</p> <p>14 MR. SLATER: Could you scroll</p> <p>15 up, please, Cheryl, the top of the</p> <p>16 second page? Thanks.</p> <p>17 Q. -- just to be clear, he</p> <p>18 specifically said that "It is similar to the</p> <p>19 NDMA that occurs in valsartan when quenched</p> <p>20 with sodium nitrite," and it's very toxic.</p> <p>21 A. That's -- he's, you know, you</p> <p>22 know -- yeah, he's making a guess. Yeah,</p> <p>23 because -- because, you know, what he found</p> <p>24 is, you know, is this N-, you know, nitroso</p>	<p style="text-align: right;">Page 101</p> <p>1 it's going to be very toxic, and that's going</p> <p>2 to be a significant GMP problem, right?</p> <p>3 That's what he said in this</p> <p>4 e-mail, correct?</p> <p>5 A. He said that; but, again, you</p> <p>6 know, he's not a toxicologist, right? And</p> <p>7 now we know, you know, based upon, you know,</p> <p>8 some of the FDA's training -- you know,</p> <p>9 training material, not all, you know,</p> <p>10 N-nitroso compound are, you know, as toxic,</p> <p>11 okay.</p> <p>12 Quite a few of them, if you</p> <p>13 look at FDA's training, you know, PPTs there</p> <p>14 are quite of few N-nitroso compound that they</p> <p>15 are not, you know, not, you know, you know,</p> <p>16 you know, genotoxic, or they are not</p> <p>17 mutagenic.</p> <p>18 So, again, you know, yeah, he's</p> <p>19 making, you know, you know, his own judgment,</p> <p>20 you know, outside of his, you know, you know,</p> <p>21 you know, expertise.</p> <p>22 Q. He turned out to be correct,</p> <p>23 right? Because NDMA and NDEA are considered</p> <p>24 to be mutagenic/genotoxic impurities,</p>

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1 correct?

2 MR. GALLAGHER: Objection.

3 Calls for speculation.

4 You can answer.

5 A. Yeah. Right now, yeah. And

6 it's considered as probable, you know, you

7 know, carcinogenic, you know, to human. But

8 it's, you know, it's probable.

9 And also, again, based upon,

10 you know, some recent FDA's training

11 material, you know, I just went through as

12 part of the preparation.

13 And endogenously formed NDMA

14 could be, you know, somewhere between 1,000

15 or even greater than 2,000 microgram per day.

16 You know, basically, you know, those NDMA,

17 they -- you know, you know, you know, it is

18 formed, you know, inside the body, like

19 inside a human body, after, you know,

20 ingestion, you know, of regular foods.

21 Q. NDMA was being formed by the

22 manufacturing process, as we agreed earlier.

23 It was a process impurity in the valsartan,

24 correct?

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1 A. Yes.

2 Q. And it would never be

3 acceptable to have NDMA at the levels it was

4 found in your company's valsartan. That

5 would never be acceptable, that could never,

6 ever be permissible, correct?

7 MR. GALLAGHER: Objection.

8 Lacks foundation, and outside the

9 scope.

10 A. Yeah, that's not accurate,

11 okay? That's not accurate. If you look at

12 FDA's -- you know, at least the most recent,

13 you know, there is an acceptable limit for

14 NDMA or NDEA, okay?

15 BY MR. SLATER:

16 Q. Are you aware that every single

17 batch of valsartan manufactured with both the

18 sodium nitrite quenching process with TEA and

19 the zinc chloride process, that every single

20 batch exceeded the FDA's stated limits?

21 Are you aware of that?

22 MR. GALLAGHER: Objection.

23 Outside the scope.

24 A. That's not accurate, okay? You

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1 know, as I indicated for the TEA process, you

2 know, based upon my knowledge

3 retrospectively, only very limited batch, you

4 know, had NDMA exceeding, you know, the

5 limit, as well as for -- I think for the --

6 for NDEA, there's also limited numbers.

7 So for the TEA process, as far

8 as I can remember, the vast majority of the

9 batches, they still met the acceptable -- the

10 current acceptable limit, although those

11 limits are retrospective.

12 BY MR. SLATER:

13 Q. The zinc chloride process,

14 every single batch that was manufactured and

15 then sold in the United States exceeded the

16 limit set by the FDA, correct?

17 MR. GALLAGHER: Objection.

18 Outside the scope.

19 You can answer.

20 A. Okay, retrospectively, yes.

21 But, you know, to be clear, you know, there

22 was no specification before the events.

23 BY MR. SLATER:

24 Q. When Jinsheng Lin said at the

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1 end of this e-mail, "This indicates that

2 other companies have paid attention to the

3 quality problem very early on," when he was

4 referring to the 2013 patent application, and

5 then said, "So leaders please pay attention

6 to this issue," he was giving you a good

7 warning that this needed to be taken care of

8 and fixed right away, because it was a

9 serious quality problem with a very toxic

10 substance, correct?

11 MR. GALLAGHER: Objection.

12 Vague, and mischaracterizes the

13 document.

14 A. As I said, you know, you know,

15 now looking back, you know, you know, he's

16 making, you know, his judgment, okay.

17 Also, he's -- you know,

18 particularly with regard to the potential

19 toxicity of NDMA, because he's not a

20 toxicologist.

21 BY MR. SLATER:

22 Q. Well, he was right that this

23 was a quality problem and that it needed to

24 be taken care of. That was a good decision

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1 by him to recommend to you and the other  
2 leaders to fix this problem, this quality  
3 problem, in 2017, right?  
4 MR. GALLAGHER: Objection.  
5 Vague, and calls for speculation.  
6 A. Again, as I said, you know,  
7 he's making, you know, you know, those  
8 guesses.  
9 BY MR. SLATER:  
10 Q. Whatever you want to call it,  
11 he was correct, right?  
12 A. Again, you know, he's making  
13 those speculations outside of his, you know,  
14 expertise.  
15 Q. Let's go to -- well, rephrase.  
16 Let me just tie this up.  
17 When people outside ZHP found  
18 out what ZHP knew at least as of July 2017,  
19 and likely earlier, since he's talking about  
20 what was already known, when the rest of the  
21 world found out about it, you couldn't sell  
22 your valsartan anymore because of the  
23 contamination with the NDMA, correct?  
24 MR. GALLAGHER: Objection.

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1 Vague, and outside the scope.  
2 A. Again, you know, as I said,  
3 he's making his speculations.  
4 BY MR. SLATER:  
5 Q. Well, whatever you want to call  
6 it, he was correct that the sodium nitrite  
7 quenching was creating nitrosamines, which  
8 was a serious GMP problem, correct?  
9 MR. GALLAGHER: Objection.  
10 Vague, and outside the scope.  
11 You can answer.  
12 A. In terms of a GMP, you know,  
13 Ms. Ge would be in a better position, you  
14 know, to answer that.  
15 MR. SLATER: Let's go, Cheryll,  
16 if we could, to the patent application  
17 referred to here. Let's go to the  
18 English version.  
19 (Whereupon, Exhibit Numbers  
20 ZHP-297 and ZHP-298 were marked for  
21 identification.)  
22 BY MR. SLATER:  
23 Q. We're just getting the document  
24 up. Great.

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1 So I can represent to you that  
2 on the metadata, this is the attachment  
3 referred to as the patent application. Do  
4 you see that? With an application  
5 announcement date of March 5, 2014 in the top  
6 right.  
7 A. Yes.  
8 MR. SLATER: And just for the  
9 record, Cheryll, could you scroll to  
10 the bottom, and we'll just read off  
11 the Bates number that is printed on  
12 this?  
13 It says ZHP01812101.  
14 Now, if you could scroll down a  
15 little more, Cheryll. Let's just get  
16 the abstract fully shown here. No,  
17 no, the other way. The other up.  
18 Perfect.  
19 Q. Looking at the Abstract of this  
20 patent application, I want to go down to the  
21 last long sentence at the bottom, and it says  
22 starting six lines from the bottom, "In the  
23 method of the present invention, the use of  
24 hypochlorite can cut off the source of

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1 nitrous acid and eliminate the generation of  
2 valsartan impurity K, and, with the  
3 adjustment of other conditions, it can  
4 prevent the generation of other impurities  
5 that are difficult to handle, allowing the  
6 preparation of high-purity valsartan  
7 products."  
8 Do you see that?  
9 A. Mm-hmm.  
10 Q. And per the e-mail that we just  
11 went through from Mr. Lin, he talked about  
12 how the people who filed this patent at this  
13 other company actually were looking at a way  
14 to prevent these nitrosamine impurities from  
15 forming by substituting something else for  
16 sodium nitrite.  
17 Do you recall we just went  
18 through that?  
19 A. Yes. But here, you know, you  
20 know, based upon what I see here, right, this  
21 patent is specifically, you know, talking  
22 about, you know, the impurity K, okay?  
23 So retrospectively we know  
24 that, you know, the impurity K is an

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1 N-nitroso impurity, right, but that impurity,  
 2 it looks like, you know, you know, Novartis,  
 3 they already knew, right, during their  
 4 initial filing. Okay. And also they did an  
 5 Ames test of the so-called impurity K, and it  
 6 turns out, you know, the Ames test results  
 7 was negative, right?  
 8 So according to a European, you  
 9 know, authority document, this impurity, you  
 10 know, you know, has been controlled as a  
 11 regular normal impurity, okay, at the level  
 12 of 1,000 ppm.  
 13 Q. I guess we could talk about  
 14 that for a moment.  
 15 You realize that whatever the  
 16 results of the Ames test was, the regulatory  
 17 authorities said it should be treated as a  
 18 mutagenic genotoxic impurity, correct?  
 19 MR. GALLAGHER: Objection.  
 20 Foundation, calls for speculation, and  
 21 outside the scope.  
 22 You can answer.  
 23 A. According to M7, if the results  
 24 of Ames test, if it's negative, you could

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1 control that or treat that as a regular  
 2 impurity.  
 3 So in this particular case,  
 4 impurity K has been treated by Novartis,  
 5 which is the original innovator of valsartan  
 6 as a regular impurity. So its level is at  
 7 1,000 ppm.  
 8 BY MR. SLATER:  
 9 Q. Let's look at -- well,  
 10 rephrase.  
 11 You're aware that the  
 12 regulatory authorities actually determined  
 13 not to treat it as a regular impurity and  
 14 said it had to be treated as a genotoxic  
 15 impurity, correct?  
 16 MR. GALLAGHER: Objection.  
 17 A. Not for -- sorry.  
 18 MR. GALLAGHER: Go ahead.  
 19 Outside the scope.  
 20 You can answer.  
 21 A. Yeah, not for impurity K. As I  
 22 said, impurity K has been controlled as a  
 23 regular impurity, although it is N-nitroso  
 24 impurities.

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1 BY MR. SLATER:  
 2 Q. NDMA and NDEA are not treated  
 3 as regular impurities; they're treated as  
 4 what they are, potent genotoxic impurities,  
 5 correct?  
 6 MR. GALLAGHER: Objection.  
 7 Vague, and calls for speculation.  
 8 A. They are different. NDMA, you  
 9 know, you know, you know, every N-nitroso  
 10 compound, they are different. As I, you  
 11 know, early -- you know, you know, early on,  
 12 as I indicated, there are quite a few, you  
 13 know, N-nitroso, you know, compounds, they  
 14 are not mutagenic.  
 15 MR. SLATER: Hang on. Let's  
 16 see where I want to go to now in this  
 17 document.  
 18 Let's go to page 5,  
 19 paragraph 17, please. No, we're way  
 20 past it. Paragraph 17. I see what  
 21 you're doing, actually. You're right.  
 22 There you go. Perfect.  
 23 Q. Paragraph -- or Section --  
 24 rephrase.

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1 Section 17 is talking about --  
 2 well, actually, let's go -- yeah, all right.  
 3 Rephrase.  
 4 In 17 it talks about, "In the  
 5 present invention, the improvement of Step 3  
 6 reaction can effectively prevent valsartan  
 7 impurity K from forming; since valsartan  
 8 impurity K is a nitroso compound that is  
 9 highly toxic, the control of impurity K in  
 10 valsartan so that it is not detected is the  
 11 objective of the valsartan preparation method  
 12 of the present invention."  
 13 Do you see what I just read?  
 14 A. Yes.  
 15 MR. SLATER: Now let's go, if  
 16 we could, to paragraph number 33.  
 17 Q. It says in paragraph 33,  
 18 starting in the second sentence, "Through the  
 19 control of the reaction conditions, the  
 20 valsartan product is synthesized while the  
 21 formation of other impurities is minimized,  
 22 allowing effective control of the content of  
 23 impurities, thereby preparing high-purity  
 24 valsartan products, and enhancing their



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1 quality, which is of great significance for  
 2 ensuring the safety of valsartan APIs."  
 3 Do you see that?  
 4 A. Mm-hmm.  
 5 Q. And you would certainly agree  
 6 with me that if you could prevent the  
 7 creation of nitrosamines by substituting  
 8 something for sodium nitrite, that's good for  
 9 safety, correct?  
 10 A. This is something unknown, and  
 11 it's speculative. Because if you use other  
 12 quenching, you know, reagent, you might  
 13 create something new, some -- you know, some  
 14 new problems, okay.  
 15 Q. That's why you test it and  
 16 study it before you sell it on the market for  
 17 patients to take it, right?  
 18 MR. GALLAGHER: Objection.  
 19 Vague.  
 20 A. Yes. You will do the -- yeah,  
 21 you will do the risk analysis. But based  
 22 upon the claim, you know, you know, in this  
 23 patent, you know, particularly with regard to  
 24 impurity K, you know, they claim is highly

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1 toxic, but actually it is not based upon, you  
 2 know, the knowledge that we know today.  
 3 BY MR. SLATER:  
 4 Q. Well, you're not saying NDMA  
 5 and NDEA aren't toxic, because they're  
 6 accepted to be highly toxic and unacceptable  
 7 to be included in the API.  
 8 A. Well, I am -- the focus of this  
 9 patent is, you know, is impurity K, okay. So  
 10 anything, you know, you know, beyond that,  
 11 you know, is their speculation, right?  
 12 And also, you know, they claim  
 13 vitamin -- I'm sorry -- the impurity K, you  
 14 know, is highly toxic, you know, based upon,  
 15 you know, whatever, you know, available from  
 16 either European regulatory, you know, you  
 17 know, agency, I think this statement is not  
 18 correct.  
 19 Q. We've confirmed as through the  
 20 e-mail we went through from Mr. Lin earlier  
 21 that your company had this patent in its  
 22 files, correct?  
 23 A. You know, right. It looks like  
 24 at least Mr. Lin has it. I don't know --

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1 yeah. Well, he sent it to other people.  
 2 Yeah.  
 3 Q. And this would have been  
 4 available to and would have been reviewed by  
 5 your company most likely in 2014 when it was  
 6 available to be seen, correct?  
 7 A. I don't know.  
 8 MR. GALLAGHER: Objection.  
 9 Calls for speculation.  
 10 MR. SLATER: All right. Let's  
 11 go to the next document. We can take  
 12 this down. Cheryll, let's go to  
 13 ZHP02336567.  
 14 (Whereupon, Exhibit Number  
 15 ZHP-299 were marked for  
 16 identification.)  
 17 BY MR. SLATER:  
 18 Q. Do you see that on the screen?  
 19 A. Mm-hmm.  
 20 Q. Okay. You see the title is  
 21 "Valsartan Patent Investigation Report"? Is  
 22 that a fair reading of that?  
 23 A. Yeah, it's accurate.  
 24 Q. And if you turn now to the next

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1 page -- and we didn't bring up the whole  
 2 document for time's sake, but let's go to the  
 3 second page of this document, which is page  
 4 ZHP02336682.  
 5 You can see in the middle of  
 6 the page the patent number of CN 103613558,  
 7 which is the patent number that was on the  
 8 patent we just looked at.  
 9 Do you see that?  
 10 A. Mm-hmm.  
 11 MR. GALLAGHER: I'm going to  
 12 object to the extent this document --  
 13 it appears you're representing that  
 14 this document is incomplete, so I'm  
 15 just going to object to that extent.  
 16 But you can proceed with your  
 17 questions.  
 18 MR. SLATER: What I'm  
 19 representing is that we have the front  
 20 for you, and we have this page,  
 21 because that's what we wanted to talk  
 22 about. But we certainly can provide  
 23 you the entire document if you want at  
 24 the break, if you want to go through

<p style="text-align: right;">Page 118</p> <p>1 it. We were just wanting to focus on                  2 this for time purposes.                  3 MR. GALLAGHER: I'm just making                  4 clear for the record, you know, if                  5 your questions -- you're happy with an                  6 incomplete document.                  7 MR. SLATER: Are you objecting                  8 to my use of the document in this                  9 form?                  10 MR. GALLAGHER: I'm just noting                  11 an objection that the document is                  12 incomplete. I don't know what is in                  13 the rest of the document. If for your                  14 questions you feel like the cover page                  15 and this page is insufficient --                  16 BY MR. SLATER:                  17 Q. Okay. So looking now at the                  18 section we're talking about now, it says the                  19 title of the invention was "A Method for                  20 Preparing Valsartan," correct?                  21 A. Yes.                  22 Q. The applicant was Zhejiang                  23 Second Pharma Company, Limited, correct?                  24 A. Yes.</p>	<p style="text-align: right;">Page 120</p> <p>1 looks like, you know, based upon the material                  2 that you just showed, you know, it just                  3 didn't specifically mention, you know,                  4 anything else. You know, it just vaguely                  5 say, you know, for all other or other                  6 impurities, but it just -- there is no                  7 specification, you know, specifics.                  8 BY MR. SLATER:                  9 Q. I'm just honestly trying to                  10 just establish the time period when it was                  11 reviewed.                  12 A. Yeah, that's fine. Yeah, yeah,                  13 that's fine, yeah.                  14 Q. Okay. So you could agree based                  15 on what I've told you this was reviewed                  16 likely in 2014 by someone in your company,                  17 correct?                  18 MR. GALLAGHER: Objection.                  19 Foundation, and calls for speculation.                  20 A. It looks like it.                  21 MR. SLATER: I think we have --                  22 Cheryll, do you have the second                  23 document also where this is referred                  24 to, the second ZHP document?</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. And if you go down to the                  2 bottom so that we can cut to the chase, it                  3 says, "Patent infringement analysis. The                  4 Huahai process does not add sodium                  5 hypochlorite, so it does not constitute an                  6 infringement."                  7 Do you see that?                  8 A. Mm-hmm.                  9 Q. And I can tell you from the                  10 metadata this document was last modified                  11 November 4, 2014, according to the document.                  12 If that's what the metadata                  13 shows, you would expect that your company had                  14 access to and reviewed that patent in 2014,                  15 correct?                  16 MR. GALLAGHER: Objection.                  17 Foundation, and compound.                  18 A. It looks like this -- you know,                  19 you know, we have a patent group, okay, and                  20 it looks like this is a report generated, you                  21 know, by that patent, you know, group, okay.                  22 And again, you know, this                  23 particular patent, the focus is related to                  24 impurity K. Okay. It didn't even -- yeah,</p>	<p style="text-align: right;">Page 121</p> <p>1 We don't have to go to that,                  2 actually. We're going to go to the                  3 next document. Oh, you have it. Oh,                  4 you know what? You put it up. You're                  5 so quick, I can't waste that effort.                  6 (Whereupon, Exhibit Number                  7 ZHP-300 was marked for                  8 identification.)                  9 BY MR. SLATER:                  10 Q. On the screen is ZHP02336432,                  11 which is a summary of patents for a patent                  12 search. And I can tell you based on the                  13 metadata this was modified May 23, 2014.                  14 That's what the metadata shows,                  15 okay?                  16 A. Okay.                  17 Q. And if we go to the second page                  18 of this document, the bottom of the page,                  19 number 4, you can see that this is a                  20 discussion of the same patent you see that                  21 we've been talking about.                  22 Do you see that? Same number,                  23 CN 103613558. Do you see that?                  24 A. Where? I'm sorry. Where</p>



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1 exactly the number?  
2 Q. Right in the middle of the  
3 page. I mean right in the middle of the  
4 "From" section.  
5 A. Oh, yeah, yeah, yeah. Okay,  
6 yeah. I saw that, mm-hmm.  
7 Q. And this document, which was  
8 compiled in 2014 within ZHP, at the very end  
9 of that description says, "The method  
10 inhibits the generation of valsartan impurity  
11 K and other impurities hard to treat, so as  
12 to yield high-purity valsartan."  
13 Do you see that?  
14 MR. GALLAGHER: Objection.  
15 Foundation, and calls for speculation.  
16 A. I'm sorry, where the language?  
17 BY MR. SLATER:  
18 Q. The last sentence.  
19 A. Last sentence, "and other  
20 impurities hard to treat so as to" -- okay,  
21 yeah.  
22 Q. So at the very least, ZHP was  
23 aware, at least as of 2014, that there were  
24 other companies out there trying to eliminate

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1 the quality problem created by having  
2 nitrosamines yielded through sodium nitrite  
3 quenching.  
4 Your company would have been  
5 aware that others were doing that, correct?  
6 MR. GALLAGHER: Objection.  
7 Foundation, and mischaracterizes the  
8 document and the testimony.  
9 A. It looks like somebody in the  
10 company, yeah, aware of this patent. But  
11 again, you know, this patent, as I said, is  
12 focused on impurity K.  
13 MR. SLATER: All right. The  
14 next document I have is probably going  
15 to take a little while, and I think  
16 I've been going about an hour. I'm  
17 happy to keep going. I'm going to  
18 need 15, 20 minutes at least for the  
19 next document. So you tell me,  
20 Patrick.  
21 MR. GALLAGHER: Dr. Li, it's  
22 really up to you. Do you want to take  
23 a break now, or do you want to go for  
24 another 15 minutes?

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1 MR. SLATER: We can take a  
2 break now, yes.  
3 Go off the record then.  
4 THE VIDEOGRAPHER: The time  
5 right now is 9:24 a.m., and we're off  
6 the record.  
7 (Whereupon, a recess was  
8 taken.)  
9 (Whereupon, Exhibit Number  
10 ZHP-301 was marked for  
11 identification.)  
12 THE VIDEOGRAPHER: The time  
13 right now is 9:43 a.m. We're back on  
14 the record.  
15 BY MR. SLATER:  
16 Q. On the screen we have  
17 Exhibit 301, an e-mail from December 22,  
18 2018.  
19 Do you see that?  
20 A. Yes, mm-hmm.  
21 MR. GALLAGHER: Adam, is there  
22 an English language version of this  
23 document?  
24 MR. SLATER: That's a good

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1 question. I don't know.  
2 Let's go off for a second. If  
3 there isn't, we'll create one right  
4 now.  
5 THE VIDEOGRAPHER: Off the  
6 record?  
7 MR. SLATER: Yes.  
8 THE VIDEOGRAPHER: The time  
9 right now is 9:44 a.m. We're off the  
10 record.  
11 (Off the record discussion.)  
12 (Whereupon, Exhibit Number  
13 ZHP-302 was marked for  
14 identification.)  
15 THE VIDEOGRAPHER: The time  
16 right now is 9:44 a.m. We're back on  
17 the record.  
18 BY MR. SLATER:  
19 Q. Looking now at this e-mail --  
20 rephrase.  
21 Looking at Exhibit 301, it's an  
22 e-mail that was sent to you and a few other  
23 people on December 22, 2018, is that correct?  
24 A. Yes.

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1 Q. Who was the e-mail written by?  
2 A. Also from Mr. Lin.  
3 Q. The same person who wrote that  
4 e-mail of July 27, 2017 that we went through  
5 earlier?  
6 A. Mm-hmm.  
7 Q. And he writes to yourself, and  
8 who else is copied? Who else was this  
9 written to?  
10 A. Mr., you know, Zhu and Chen,  
11 Chen Wenbin, yeah.  
12 Q. Who are those people? Let's  
13 take them one at a time, if you could,  
14 please.  
15 A. These two, Mr. Zhu and also  
16 Mr. Chen, Mr. Zhu is actually my direct  
17 report.  
18 Q. He reports to you?  
19 A. Yes.  
20 Q. What's his title?  
21 A. He is -- the title is the  
22 director for CEMAT, yeah. Analytical --  
23 yeah.  
24 Q. I'm sorry. You said

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1 "analytical" --  
2 A. It should be director of  
3 analytical chemistry or something like that,  
4 or just, you know, director of analysis,  
5 yeah. In Chinese we call (speaking Chinese).  
6 Q. And the other person, Mr. Chen,  
7 who is that?  
8 A. He is under Mr. Zhu. He is the  
9 associate -- yeah, should be the associate  
10 director, yeah.  
11 Q. And tell me if I understand  
12 what this e-mail is saying. It has -- first  
13 of all, it has an attachment, which we're  
14 going to get to in a moment.  
15 It is a summary of CEMAT  
16 projects with a long report review cycle.  
17 Do I understand that?  
18 A. Right. Right.  
19 Q. The e-mail reads -- rephrase.  
20 The e-mail reads, "Mr. Li:  
21 Attached please find the summary of 27 recent  
22 projects with a report review cycle of more  
23 than two months, including 16 impurity  
24 studies, one solid-state analysis, three

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1 structural confirmations, and seven  
2 genotoxicity assessments. I hope to  
3 communicate with you and find a way to  
4 shorten the report review cycle, thank you."  
5 Did I read that in a fairly  
6 accurate way?  
7 A. Yes.  
8 Q. And it was signed by Jinsheng  
9 Lin at CEMAT, December 22, 2018, correct?  
10 A. Yes.  
11 MR. SLATER: Let's now go to  
12 the attachment, which is the summary  
13 of the CEMAT projects with a long  
14 report review cycle.  
15 THE WITNESS: Okay.  
16 MR. SLATER: And that will be  
17 Exhibit 302.  
18 THE STENOGRAPHER: I think it's  
19 303. 302 was the English version.  
20 303.  
21 MR. SLATER: Thank you.  
22 (Whereupon, Exhibit Number  
23 ZHP-303 was marked for  
24 identification.)

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1 A. Could you enlarge? It's really  
2 difficult to see from my end.  
3 BY MR. SLATER:  
4 Q. We're going to when we scroll  
5 up to it.  
6 MR. SLATER: But I also --  
7 Patrick, if you'd like, I think we  
8 have an English version of this  
9 machine translated, is that correct?  
10 MR. GALLAGHER: That would be  
11 awesome if you do.  
12 MR. SLATER: So we'll load that  
13 up before I ask any questions.  
14 Let me know, Cheryll, when it's  
15 been loaded.  
16 MR. GALLAGHER: There it is.  
17 You're good to go.  
18 (Whereupon, Exhibit Number  
19 ZHP-304 was marked for  
20 identification.)  
21 MR. SLATER: So looking now at  
22 this spreadsheet, let's go, if we  
23 could, to Tab 1.3, Row 53. Perfect.  
24 Scroll down a millimeter. Do we have

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1 the top of 53?  
 2 Sorry, I shouldn't have made  
 3 you do it.  
 4 A. Go the other way. Could you  
 5 make it bigger?  
 6 BY MR. SLATER:  
 7 Q. We'll make it bigger and work  
 8 our way down?  
 9 A. Could you make it even bigger?  
 10 MS. CALDERON: Give me one  
 11 second. I'm working on it.  
 12 THE WITNESS: Okay.  
 13 MR. SLATER: Just make it  
 14 bigger and then we'll scroll through  
 15 it as we go, so you don't have to try  
 16 to fit the whole thing on one page.  
 17 Make it nice and big. There we go.  
 18 MS. CALDERON: Sorry.  
 19 MR. SLATER: Don't worry about  
 20 it. No one else can do it.  
 21 MS. CALDERON: Obviously I  
 22 can't either.  
 23 MR. SLATER: Keep going. You  
 24 got it. You're going slowly down.

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1 Now you're at 172 again.  
 2 MS. CALDERON: That's it.  
 3 MR. SLATER: Thank you.  
 4 BY MR. SLATER:  
 5 Q. Okay. Looking now in Box 53,  
 6 at the top it talks about Investigation on  
 7 the RT 26-minute impurity in irbesartan crude  
 8 product.  
 9 Do you see that?  
 10 A. Mm-hmm.  
 11 Q. It says the responsible person  
 12 was Tianpei Huang, new project in July 2017,  
 13 completed in April and no longer updated in  
 14 May.  
 15 Do you see that?  
 16 A. Mm-hmm.  
 17 Q. And again, who is Mr. Huang?  
 18 A. She is one of the analysts at  
 19 the time.  
 20 Q. She was an analyst at CEMAT?  
 21 A. Yes. She was, actually.  
 22 Q. It says, "The project was  
 23 authorized by the Technology Department of  
 24 Chuannan in Plant 1."

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1 Do you see that?  
 2 A. I'm sorry, where?  
 3 Q. Where we just read. It says,  
 4 "The project was authorized by the technology  
 5 department of Chuannan in Plant 1."  
 6 A. Which line?  
 7 Q. Right after I just read about  
 8 "no longer updated in May" in red.  
 9 A. Wait a second. Oh, the red,  
 10 okay. Yeah. Yeah, they actually, yeah, ask  
 11 CEMAT to do the investigation, yes.  
 12 Q. So how does that work? You  
 13 have Chuannan and Xunqiao, if I'm pronouncing  
 14 those right, if they have something like an  
 15 impurity investigation they need to do, they  
 16 ask CEMAT to do that work for them?  
 17 A. Well, sometimes they will do by  
 18 themselves along with, you know, Chuannan QC.  
 19 But if they cannot resolve, yeah, they  
 20 usually send it to us.  
 21 Q. And then I'm going to read a  
 22 little further. It says, "Due to the  
 23 incomplete quenching of sodium azide caused  
 24 by the separate treatment of irbesartan

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1 sodium azide wastewater, there is a frequent  
 2 occurrence of muffled explosion in the  
 3 production process, so the technology  
 4 department carried out the technical  
 5 improvement by which the sodium azide  
 6 quenching takes place in the unstratified  
 7 step in the crude irbesartan process."  
 8 Do I have that correct?  
 9 MR. GALLAGHER: I'm going to  
 10 object to this as outside the scope.  
 11 But please answer to the extent  
 12 you know and can.  
 13 A. Yeah.  
 14 BY MR. SLATER:  
 15 Q. It then continues -- and, by  
 16 the way, when it talks about the  
 17 "unstratified step in the crude irbesartan  
 18 process," what does that refer to,  
 19 "unstratified," in that context?  
 20 A. Unstratified. I'm sorry, I  
 21 don't understand exactly what you mean by  
 22 "unstratified."  
 23 Q. Well, I'll ask the question  
 24 differently then. Let me just continue.

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1 It continues, "However, after  
2 the improvement there is an unknown impurity  
3 of about 0.5 percent at 26 minutes in the  
4 crude irbesartan, and the structure of this  
5 impurity needs to be investigated."  
6 Do you see that?  
7 MR. GALLAGHER: Again, I'm  
8 going to object as outside the scope.  
9 But please answer to the extent  
10 you know and can.  
11 A. So could you point out exactly,  
12 like, which line? I'm sorry. Because, you  
13 know, the English and the Chinese, you know,  
14 version --  
15 BY MR. SLATER:  
16 Q. Can I point out exactly what  
17 line? I'm not going to be able to point out  
18 exactly what line. How about this is all  
19 above the "July Process Update."  
20 Do you see that?  
21 A. Let me -- how about let me --  
22 you know, let me take a little bit of time  
23 and read this through, okay?  
24 Q. Sure. Let's go off the timer,

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1 and you can take a look, and then we'll walk  
2 through it a little more generally. That's a  
3 good idea?  
4 A. Okay.  
5 MR. SLATER: Stay on the  
6 record, off the clock. No problem.  
7 (Witness reviewing document.)  
8 THE WITNESS: Okay. I  
9 basically read through. We can go  
10 ahead.  
11 BY MR. SLATER:  
12 Q. I'll start over.  
13 In this Box 53, you can see  
14 there's a discussion of the investigation of  
15 the impurity in the irbesartan crude product  
16 that we were talking about per that prior  
17 e-mail that Jinsheng Lin wrote, correct?  
18 MR. GALLAGHER: I'm going to  
19 object to the questioning about this  
20 box as outside the scope so I don't  
21 have to keep repeating it.  
22 MR. SLATER: That's fine.  
23 You've got that objection.  
24 ///

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1 BY MR. SLATER:  
2 Q. And you said "correct," right,  
3 Dr. Li?  
4 A. I'm sorry, say that again?  
5 Q. What they're discussing in this  
6 Box 53 is a study, a research project that  
7 was being performed that followed from that  
8 e-mail that Jinsheng Lin wrote that we talked  
9 about a few minutes earlier, correct?  
10 A. It looks like.  
11 Q. Then there's process updates  
12 going forward. And it shows, for example, in  
13 July, in part it says that "Based on the  
14 process of generation, the impurity should be  
15 a nitroso compound in irbesartan. The  
16 degradation experiment is currently being  
17 carried out, and subsequently the sample will  
18 be prepared."  
19 That's correct in part, right?  
20 A. Mm-hmm.  
21 Q. And when they refer to "a  
22 nitroso compound," we're talking about a  
23 nitrosamine, correct?  
24 A. This nitrosamine is the nitroso

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1 compound on the irbesartan, okay. It's very  
2 specific.  
3 Q. Then there's an August process  
4 update in August 2017 that said, "The forced  
5 degradation experiment proved that the  
6 impurity was a result of the reaction of  
7 irbesartan with sodium nitrite and  
8 hydrochloric acid. At present, the impurity  
9 has been prepared by thin layer  
10 chromatography."  
11 Do I have that correct?  
12 A. Yes.  
13 Q. Then in September there's a  
14 process update that says, "The impurity  
15 standard production has been separated and  
16 was sent to Dan Li for nuclear magnetic  
17 resonance."  
18 My first question is, who is  
19 Dan Li?  
20 A. She is a person specializing in  
21 NMR structure characterization, or nuclear  
22 magnetic resonance.  
23 Q. And what's the purpose of that  
24 test in this context? What would that be

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1 trying to show?

2 A. Trying to elucidate, you know,

3 the structure.

4 Q. The structure of the

5 nitrosamine?

6 A. No, that particular, you know,

7 nitroso compound with irbesartan.

8 Q. And then it points out that

9 there was a malfunction of the equipment so

10 the test couldn't start at that time.

11 Do I have that right?

12 A. Yes.

13 Q. And then if we go forward,

14 there are updates in October and November,

15 and then in December it says the research

16 report is being completed, correct?

17 A. Yes.

18 Q. And then in January, now

19 January 2018, it says that the research

20 report was completed pending review, correct?

21 A. Correct.

22 Q. Then we go forward into March.

23 There's no update in March, right? Just

24 says, "No update"?

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1 A. Right.

2 Q. And then in April it says,

3 "After discussing with Mr. Li, as the project

4 involves an impurity that is sensitive so no

5 research report will be issued and no further

6 updates will be made." Correct?

7 A. It looks like so.

8 Q. So you instructed that this

9 research project not go forward any further

10 and no report to be issued, as documented

11 here, correct?

12 MR. GALLAGHER: Objection.

13 Foundation, and assumes facts.

14 BY MR. SLATER:

15 Q. That is what it says, correct?

16 A. Based upon what it says, yeah,

17 it looks like so.

18 Q. Do you know where that report

19 is?

20 A. I don't recall.

21 Q. Where would we look to find

22 that report? Because I can represent we've

23 been looking for it and have been unable to

24 find it.

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1 Do you have any idea where we

2 would look to find that report?

3 A. I don't -- I don't recall. You

4 know, I don't even recall this particular

5 discussion. I mean, you know, this so long,

6 you know, you can see there's so many

7 projects, you know, ongoing. So I really

8 don't, you know, remember the specifics.

9 Q. And, again, this says that the

10 reason why the research report was not to be

11 issued and not to be updated any further was

12 after discussing with you, you had pointed

13 out that the project involves an impurity

14 that is sensitive.

15 That's what the document shows,

16 correct?

17 A. It looks like so.

18 Q. And reading that doesn't

19 refresh your recollection of telling your

20 team to -- not to do anything further with

21 the report and not to issue it? You don't

22 recall that?

23 A. As I said, I don't remember,

24 you know, the specifics. Maybe the reason

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1 is, you know, you know, I can -- maybe the

2 reason is basically this is not, you know,

3 relevant to a real process, right? Because

4 this is a trial and, you know, they -- you

5 know, during the trial they change the way of

6 the -- you know, of the quenching, right?

7 So, yeah, so basically, you

8 know, you know, this compound would not be

9 present in a normal registered, you know, the

10 process.

11 So maybe I want to just, you

12 know, ask them to -- because issuing this

13 could be -- could have caused some confusion.

14 You know, people may confuse the presence of

15 this particular impurity with the registered,

16 you know, process.

17 Q. You testified a few moments ago

18 you don't recall this at all. So everything

19 you're telling me about what might have

20 happened --

21 A. This is what I'm trying to --

22 you know, it's a -- you know, what I'm trying

23 to, you know, you know, reconfigure, you

24 know, a possible scenario. You know, this is



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1 not, you know, you know, what really may  
2 happen. You know what I'm saying? It's  
3 just, you know, give some, you know,  
4 speculation, you know what I'm saying?  
5 But, yeah, definitely I don't  
6 remember exactly, you know, what I had said  
7 during that particular time. Okay?  
8 Q. Well, this document certainly  
9 sets forth that you were concerned at the  
10 time that the impurity was a sensitive  
11 impurity, and that would be talking about a  
12 nitrosamine impurity; that you were concerned  
13 about that, right?  
14 A. Well, as I said, you know, you  
15 know, the possible reason, right? As I said,  
16 it's a possible reason.  
17 You know, maybe I wanted to  
18 avoid, you know, the confusion of an  
19 impurity, you know, from this trial, you  
20 know, process, with an impurity from the real  
21 ones. Okay.  
22 But again, look at this  
23 particular, you know, impurity, you know,  
24 this particular impurity itself, you know, if

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1 you look at a structure, it's not a typical  
2 N-nitroso compound, okay?  
3 And based upon everything that  
4 we have know, you know, for now, you know,  
5 you know, if we were to do an Ames test on  
6 this particular, you know, nitroso compound  
7 of irbesartan, I would say, you know, you  
8 know, you know, a reasonable projection  
9 was -- you know, would be the Ames would very  
10 be likely be negative, okay, you know, based  
11 upon everything, you know, that we know by  
12 now, you know, based upon what they call a  
13 QSAR, quantitative structure-activity  
14 analysis.  
15 You know, I mean, it's the same  
16 thing like impurity K, right? Because, you  
17 know, see, the reason is why those compounds  
18 may be Ames negative is because you have  
19 to -- you know, when you look at the activity  
20 of a compound, you know, one of the things  
21 you also have to look at is the serial  
22 chemistry, right?  
23 So based upon the knowledge  
24 that we have, you know, gained, you know, up

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1 to now, you know, for those, you know, like  
2 large molecule and nitroso compound,  
3 particularly with substituents surrounding  
4 the, you know, nitroso compound, if they are  
5 big, typically you tend to have this kind of  
6 a, you know, nitroso compound to be Ames  
7 negative.  
8 Q. At this time, as documented --  
9 well, rephrase. I want to just go over a  
10 couple of basic facts that we have here,  
11 okay?  
12 A. Mm-hmm.  
13 Q. One of the things we know is  
14 that this demonstrates, as did the e-mail we  
15 went through before, that ZHP was aware that  
16 the sodium nitrite quenching was creating  
17 nitrosamine impurities. That you knew.  
18 A. We knew based upon this  
19 document --  
20 MR. GALLAGHER: Objection.  
21 Misstates the testimony.  
22 Go ahead. Go ahead.  
23 A. I'm sorry.  
24 Based upon document, yeah, we

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1 knew specifically the nitroso compound of  
2 irbesartan, okay. And also, irbesartan is  
3 the main ingredient of that particular  
4 reaction.  
5 Q. And you also knew per the  
6 e-mail we went through that NDMA occurs in  
7 valsartan when it was quenched with sodium  
8 nitrite. That was known as of July 2017.  
9 That's why that was stated by Jen Sheng Lin,  
10 correct?  
11 MR. GALLAGHER: Objection.  
12 Mischaracterizes.  
13 A. As I told you, you know, you  
14 know, for that e-mail, you know, I do not  
15 recall. Now looking back, you know, you  
16 know, basically, as I said, anything about,  
17 you know, you know, valsartan is huge  
18 speculation because, you know, you know, the  
19 data that's shown here is specifically  
20 regarding to irbesartan.  
21 BY MR. SLATER:  
22 Q. Well, why don't we do this.  
23 Let's just -- in fairness, let's go back to  
24 the e-mail to get ourselves oriented here.

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1 A. Okay.  
 2 Q. And that was Exhibit -- gosh, I  
 3 lost track of which exhibit it was. Cheryl  
 4 knows. She's going to find it.  
 5 MS. CALDERON: Do you want me  
 6 to put it up?  
 7 MR. SLATER: I would, please.  
 8 And if we can clarify for the  
 9 record what exhibit number that was,  
 10 I'll write it on here so I won't  
 11 forget again.  
 12 MS. CALDERON: Hang on one  
 13 second. It's 295.  
 14 MR. SLATER: Great. Thank you.  
 15 And let's go to the top of the second  
 16 page again. Just -- okay.  
 17 Q. Looking now at the top of the  
 18 second page of Exhibit 295, which was an  
 19 e-mail dated July 27, 2017, from Jinsheng Lin  
 20 in your CEMAT facility, he pointed out that  
 21 what was being seen with the irbesartan is  
 22 similar to the NDMA that occurs in valsartan  
 23 when quenched with sodium nitrite.  
 24 That's part of what Jinsheng

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1 Lin said in that e-mail, correct?  
 2 A. Well, in his -- see, in the  
 3 beginning of the sentence, he said, you know,  
 4 it's likely, you know, or most likely, right?  
 5 So -- yeah, so that's a speculation.  
 6 BY MR. SLATER:  
 7 Q. Well, actually, let's walk  
 8 through it then.  
 9 What he said was, "Through the  
 10 secondary mass spectrometry analysis, it can  
 11 be inferred that the extra NO substituent is  
 12 in the cyclic compound fragment, and it is  
 13 very likely that it is an N-NO compound."  
 14 That's talking about what's  
 15 being seen in the irbesartan, correct?  
 16 A. Yes.  
 17 Q. Then after the semicolon he  
 18 states, "It is similar to the NDMA that  
 19 occurs in valsartan when quenched with sodium  
 20 nitrite," correct?  
 21 MR. GALLAGHER: Objection.  
 22 Mischaracterizes.  
 23 BY MR. SLATER:  
 24 Q. That's what it says, right?

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1 MR. GALLAGHER: I guess I want  
 2 to clarify. Are you looking at the  
 3 English language translation, or are  
 4 you looking at the actual Chinese  
 5 language document?  
 6 MR. SLATER: Well, I don't know  
 7 why that matters, honestly. You have  
 8 them.  
 9 MR. GALLAGHER: I don't see any  
 10 semicolons in the Chinese language  
 11 document.  
 12 THE WITNESS: Yeah, in the  
 13 Chinese language, it's just a regular  
 14 comma. Yeah, it's a comma.  
 15 MR. SLATER: Okay. There's a  
 16 semicolon objection. I'm going to fix  
 17 it. I'll start a new question.  
 18 BY MR. SLATER:  
 19 Q. After pointing out what we just  
 20 established had to do with irbesartan,  
 21 Mr. Lin then says, "It is similar to the NDMA  
 22 that occurs in valsartan when quenched with  
 23 sodium nitrite."  
 24 That's what he says in this

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1 document July 27, 2017, correct?  
 2 A. Yes.  
 3 Q. Do you know how long your  
 4 company knew that NDMA occurs in valsartan  
 5 when quenched with sodium nitrite, how long  
 6 before July of 2017 people in your company  
 7 knew that?  
 8 A. I don't know. Looks like only  
 9 he knows at the time.  
 10 Q. He was the one who did the  
 11 patent review, right, that we went through  
 12 before, going back to 2014 on this, right?  
 13 A. Mm-hmm.  
 14 Q. So at least this person who you  
 15 told us was a, and remains an important  
 16 person in your organization was looking at  
 17 this issue going back to 2014. We've  
 18 established that with the document, correct?  
 19 MR. GALLAGHER: Objection.  
 20 Mischaracterizes the testimony.  
 21 But please answer.  
 22 A. Yes.  
 23 BY MR. SLATER:  
 24 Q. And we also know that he was

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1 concerned -- rephrase.  
 2 And we also know that he was  
 3 concerned --  
 4 MR. SLATER: If we scroll down  
 5 to the second-to-last paragraph on  
 6 this page.  
 7 Q. -- that with regard to the  
 8 irbesartan, if it was in a nitrosamine  
 9 compound, "then its toxicity will be very  
 10 strong, and there will be an extremely high  
 11 GMP risk."  
 12 That's what he says, right?  
 13 MR. GALLAGHER: Objection.  
 14 Outside the scope.  
 15 A. Again, as I said, you know,  
 16 he's making speculation outside of his  
 17 expertise.  
 18 BY MR. SLATER:  
 19 Q. Well, what he's doing is  
 20 analyzing what we know from earlier testimony  
 21 you gave was the root cause for the NDMA  
 22 formation which was caused by the sodium  
 23 nitrite, correct?  
 24 A. Part of the -- yes.

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1 Q. So he was correct that the  
 2 sodium nitrite quenching creating  
 3 nitrosamines was a serious GMP problem.  
 4 He was correct about that,  
 5 right?  
 6 MR. GALLAGHER: Objection.  
 7 A. That's speculation.  
 8 BY MR. SLATER:  
 9 Q. Well, if you want to call it  
 10 speculation, that's fine. But it was  
 11 confirmed, and that's the root cause analysis  
 12 that you've already testified to that your  
 13 company came to, right?  
 14 A. After, you know -- yeah, after  
 15 the events, yes.  
 16 Q. Well, that's what was disclosed  
 17 after the events, but this e-mail shows that  
 18 people in your company knew about this,  
 19 including yourself when you got this e-mail,  
 20 in July of 2017, right?  
 21 A. As I said, you know, you know,  
 22 I am -- you know, I was under this, but I --  
 23 you know, as I said, I didn't have time to,  
 24 you know, go through everything and, you

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1 know, I don't recall, you know, specifically  
 2 looking through this e-mail.  
 3 Q. And, in fact, the right thing  
 4 to do at this point when you're -- rephrase.  
 5 The right thing to do -- as  
 6 soon as your company knew that nitrosamines  
 7 were being yielded by the sodium nitrite  
 8 quenching, the right thing to do would have  
 9 been to stop production and optimize the  
 10 process at that time and reveal to world  
 11 regulatory authorities this problem, right?  
 12 That would have been the right  
 13 thing to do when your company discovered this  
 14 internally, right?  
 15 MR. GALLAGHER: Objection.  
 16 Vague, outside the scope, and calls  
 17 for speculation.  
 18 A. You know, I don't know, or I  
 19 didn't know at the time how far, you know,  
 20 you know, this went through, right.  
 21 He sent to those people. I  
 22 didn't know, and I do not know, you know, how  
 23 those people -- their response. They may  
 24 ignore or they may think this -- you know,

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1 maybe he's -- Mr. Lin's speculation.  
 2 So, basically, it looks like it  
 3 didn't, you know, go far.  
 4 BY MR. SLATER:  
 5 Q. In retrospect, it's too bad it  
 6 didn't go far because the right thing to do  
 7 would have been to disclose this to the  
 8 regulatory authorities and stop production,  
 9 right?  
 10 MR. GALLAGHER: Objection.  
 11 Vague, outside the scope, calls for  
 12 speculation, and asked and answered.  
 13 THE WITNESS: I mean, do I need  
 14 to answer?  
 15 MR. GALLAGHER: Answer to the  
 16 extent -- you know, to the extent you  
 17 can.  
 18 THE WITNESS: Sure.  
 19 I mean basically, you know, for  
 20 me it's the same thing. I mean,  
 21 retrospectively, you know, you know,  
 22 it might be, but at the time people  
 23 may thought, you know, he just, you  
 24 know, making his speculations and --

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1 BY MR. SLATER:  
 2 Q. Well, looking at the last  
 3 sentence, he said -- rephrase.  
 4 Looking at the last paragraph,  
 5 he said in part, after looking at the patent  
 6 going back to 2013 and 2014 from one of your  
 7 competitors, that that indicated that other  
 8 companies had paid attention to the quality  
 9 problem very early on, and that quality  
 10 problem is sodium nitrite quenching creating  
 11 nitrosamines in your company's sartans,  
 12 including valsartan, correct?  
 13 That's what we've established,  
 14 correct?  
 15 A. Well, again --  
 16 MR. GALLAGHER: Objection.  
 17 Mischaracterizes the testimony and the  
 18 documents.  
 19 A. Right. I mean, you know, once  
 20 again, that N-nitroso compound, right,  
 21 specified in the patent, you know, was, you  
 22 know, impurity K, okay.  
 23 So this impurity K, as I said,  
 24 has been controlled as a regular impurity,

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1 okay? Its level is 1,000 ppm.  
 2 BY MR. SLATER:  
 3 Q. Is that what you believe the  
 4 FDA permitted your company -- rephrase.  
 5 Is that your understanding of  
 6 the FDA's position on that impurity?  
 7 MR. GALLAGHER: Objection.  
 8 Outside the scope.  
 9 THE WITNESS: I'm sorry. Go  
 10 ahead.  
 11 MR. GALLAGHER: Objection.  
 12 Outside the scope.  
 13 To the extent you know, please  
 14 answer.  
 15 A. Okay. I mean, FDA is well  
 16 aware of the impurity K is Ames negative,  
 17 okay.  
 18 BY MR. SLATER:  
 19 Q. I'm just asking, do you know  
 20 what the FDA's position was on the impurity  
 21 K? Do you know whether they thought it could  
 22 be handled as a regular impurity or whether  
 23 they said it had to be limited to 0.3 ppm?  
 24 Do you know?

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1 MR. GALLAGHER: Objection.  
 2 Outside the scope.  
 3 To the extent you know  
 4 personally, you can answer.  
 5 A. I do not know what FDA's, you  
 6 know, you know, specific requirement at this  
 7 time, okay? But in one of the communications  
 8 I think came, you know, from FDA last year,  
 9 they asked us to do some further in vivo  
 10 animal study on the impurity K, okay, which  
 11 we did.  
 12 We did a particular in vivo,  
 13 you know, enrolled in animal studies  
 14 according to the principle of, you know, ICH  
 15 M7, and we submitted this, you know, you  
 16 know, proposal back to FDA.  
 17 I think our proposal was to --  
 18 you know, essentially there is no need to  
 19 control at such low level. It would be  
 20 controlled, you know, based upon our current,  
 21 you know, process.  
 22 I don't remember exactly, you  
 23 know, what specific, you know, specification  
 24 that we'd propose. It could be like several

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1 hundredths of ppm.  
 2 BY MR. SLATER:  
 3 Q. Let's be clear. You're talking  
 4 about impurity K, right?  
 5 A. Right.  
 6 Q. You're not talking about NDMA  
 7 or NDEA, right?  
 8 A. No.  
 9 Q. Because those would never be  
 10 acceptable at regular levels, right?  
 11 A. Retrospectively we know, yes.  
 12 Q. And you knew that the FDA  
 13 guidances and the European guidances all said  
 14 that nitrosamine compounds needed to be  
 15 excepted from the threshold approach because  
 16 they're considered so dangerous, they  
 17 couldn't even be allowed to be included based  
 18 on the standard threshold approach.  
 19 Were you aware of that?  
 20 MR. GALLAGHER: Objection.  
 21 Outside the scope, and lack of  
 22 foundation.  
 23 A. Retrospectively, based upon M7,  
 24 yeah. That's in general. But as I said, you

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1 know, the European, you know, authority, they  
2 specifically had a discussion on impurity K,  
3 you know, in which obviously that's after,  
4 you know, these events came out.  
5 And they specifically, you  
6 know, you know, at the time at least they  
7 allow the original -- it looks like the  
8 original Novartis specification at 1,000 ppm.  
9 BY MR. SLATER:  
10 Q. Let's come back now to this  
11 e-mail where I was reading with you, where  
12 Jinsheng Lin said, "This indicates that other  
13 companies have paid attention to the quality  
14 problem very early on."  
15 Just to be clear, the quality  
16 problem was sodium nitrite quenching creating  
17 nitrosamines, correct?  
18 A. Again, as I said, he's making  
19 speculations, and that pattern is  
20 specifically talking about impurity K.  
21 Q. Well, he also talked above  
22 about NDMA forming in valsartan when it's  
23 quenched with sodium nitrite. He also  
24 pointed out that your company knew that as

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1 well.  
2 He talked about that, right?  
3 A. He talked about only he knew.  
4 I don't know anybody else at that time, you  
5 know, before his e-mail.  
6 Q. When -- well, rephrase.  
7 When you and Peng Dong and  
8 Linda Lin and the others in that e-mail got  
9 this e-mail, if that was the first time that  
10 you saw that, shouldn't that have been an  
11 alarm bell going off in your head and say,  
12 "My gosh, there's NDMA forming in our  
13 valsartan; this is a major problem"?  
14 That would have been the  
15 appropriate response, right?  
16 MR. GALLAGHER: Objection.  
17 Vague.  
18 A. I mean, retrospectively, you  
19 know, you know, if I went through or if  
20 Mr. Lin specifically came to me, you know,  
21 that might be, you know, the starting of the,  
22 you know, of the action time.  
23 But as again, you know, it  
24 looks like this e-mail just slipped through

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1 from my sight.  
2 BY MR. SLATER:  
3 Q. And slipped through Linda Lin's  
4 sight and Peng Dong? All of those, none of  
5 them did anything?  
6 A. That, I don't know. I -- you  
7 know, I have no knowledge, you know.  
8 Q. Do you know why it is that this  
9 e-mail, which was sent to Ms. Ge and to Peng  
10 Dong and Linda Lin, that it didn't show up in  
11 any of their custodial files, and none of  
12 them are listed as duplicate custodians on  
13 this document?  
14 Do you know why that happened?  
15 MR. GALLAGHER: Objection.  
16 A. I don't know.  
17 MR. GALLAGHER: Outside the  
18 scope.  
19 BY MR. SLATER:  
20 Q. You don't know?  
21 Do you know why the report  
22 that's referenced in the spreadsheet that we  
23 went through that documents in April of 2018  
24 you said, "The report will not be issued and

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1 it shouldn't be updated any further due to  
2 the sensitivity of this impurity," do you  
3 know why that report has never been produced  
4 to us?  
5 MR. GALLAGHER: Objection.  
6 Outside the scope.  
7 A. I have no idea.  
8 BY MR. SLATER:  
9 Q. One way to try to get that  
10 would be to search the custodial files of  
11 Dan Li and Tianpei Huang. They might have it  
12 in their custodial files, correct?  
13 MR. GALLAGHER: I'm going to  
14 object to these questions as  
15 argumentative, they're so far outside  
16 the scope.  
17 Why you would ask Mr. Li about  
18 searching documents of other people  
19 makes absolutely no sense.  
20 So, you know, Dr. Li, you can  
21 answer to the extent you have any  
22 knowledge of this.  
23 But, Adam, I think you need to  
24 move on.



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1 MR. SLATER: Well, these people  
 2 work for him, and he knows where they  
 3 keep their documents and how they keep  
 4 their files.  
 5 MR. GALLAGHER: Those aren't  
 6 the questions you're asking.  
 7 A. They are the first-line  
 8 analysts, okay, and they usually -- you know,  
 9 they don't talk to me, you know, very often,  
 10 you know, at my level.  
 11 BY MR. SLATER:  
 12 Q. If that report was destroyed,  
 13 would that be acceptable in terms of how your  
 14 department operates?  
 15 A. I don't know whether it's been  
 16 destroyed or not.  
 17 Q. If it was destroyed, would that  
 18 be acceptable?  
 19 A. That's a hypothetical question.  
 20 It may be destroyed or, you know, per  
 21 company's -- you know, because everyone, you  
 22 know, company has certain -- as I mentioned,  
 23 you know, you know, on the company server, if  
 24 you deleted something, you know, because from

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1 time to time your mailbox fill up, and some  
 2 people, you know, you know, they have -- may  
 3 have to have it to, you know, very often to  
 4 delete it, right?  
 5 So after, you know, certain  
 6 period of the deletion it will be  
 7 automatically, you know, like, taken from,  
 8 you know, the company server.  
 9 Q. Let's also talk about -- well,  
 10 rephrase.  
 11 We talked about the patent, and  
 12 you spoke about impurity K a bunch of times.  
 13 A. Mm-hmm.  
 14 Q. A very important message in  
 15 these e-mail and in that patent is that it  
 16 was figured out, your company knew it and  
 17 others started to figure it out on the  
 18 outside, that the way to avoid creating  
 19 nitrosamine compounds was to not quench with  
 20 sodium nitrite.  
 21 That's an important lesson  
 22 that's being discussed here, right?  
 23 MR. GALLAGHER: Objection.  
 24 Mischaracterizes the testimony and the

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1 documents.  
 2 BY MR. SLATER:  
 3 Q. I'll ask it -- there's an  
 4 objection. Let me ask a different question,  
 5 because there's an objection. So I'm going  
 6 to strive for a better question.  
 7 The -- rephrase.  
 8 Knowing that sodium nitrite  
 9 quenching in the manufacture of valsartan was  
 10 an important part of causing nitrosamines to  
 11 be formed, that was important information,  
 12 right?  
 13 MR. GALLAGHER: Objection.  
 14 Vague.  
 15 You can answer.  
 16 A. You know, again, that patent  
 17 specifically talking about impurity K, okay.  
 18 Anything else, there is no specifics.  
 19 BY MR. SLATER:  
 20 Q. Well, what it talks --  
 21 rephrase.  
 22 The patent talks about how to  
 23 avoid creating nitroso compounds. And that's  
 24 the way you avoid it, is by not quenching

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1 with sodium nitrite, correct?  
 2 A. Again, as I mentioned, every  
 3 nitroso compound, you know, is different,  
 4 okay, specifically for the impurity K. Now  
 5 we know, you know, it's, again, Ames  
 6 negative.  
 7 So, you know, so do not confuse  
 8 or replace that, you know, nitroso compound  
 9 with NDMA.  
 10 I mean, you know, in that  
 11 patent, as far as, you know, based upon the  
 12 information that you presented, you know, I  
 13 don't see so far, you know, in that patent,  
 14 there's any specific mention of NDMA in that  
 15 patent.  
 16 Q. No. What there's mention of is  
 17 that your competitor wanted to eliminate  
 18 sodium nitrite as the quenching agent and  
 19 instead used bleach so that it wouldn't form  
 20 nitrosamines as part of the process, correct?  
 21 A. I mean, again, you know --  
 22 MR. GALLAGHER: Objection.  
 23 A. -- that nitrosamine is not  
 24 NDMA, okay, is impurity K. So, you know,

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1 okay, they are different.  
2 BY MR. SLATER:  
3 Q. At the very bottom of this  
4 page, which is, I think, where we went off on  
5 this tangent, but let me bring it back and  
6 then we'll move on.  
7 At the bottom of this page  
8 Jinsheng Lin said, "This indicates that other  
9 companies have paid attention to the quality  
10 problem very early on. So leaders please pay  
11 attention to this issue."  
12 That was a warning that you  
13 said either slipped through the cracks or was  
14 ignored, but it's a warning that should have  
15 been listened to, right?  
16 MR. GALLAGHER: Objection.  
17 Mischaracterizes the testimony, and  
18 mischaracterizes the documents.  
19 A. I think I already, you know,  
20 you know, answered your question before.  
21 BY MR. SLATER:  
22 Q. Well, in retrospect, you would  
23 agree with me that whenever the company knew  
24 at some point before July of 2017 that NDMA

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1 was occurring in valsartan when quenched with  
2 sodium nitrite, you would agree that as soon  
3 as that was known, action should have been  
4 taken to stop manufacturing by that process  
5 until it could be optimized to prevent NDMA  
6 from being created, correct?  
7 MR. GALLAGHER: Objection.  
8 Vague, calls for speculation, and  
9 outside the scope.  
10 A. Again, I think I already, you  
11 know, answered your question before. I mean,  
12 if you wanted me to repeat, you know, I  
13 mean...  
14 BY MR. SLATER:  
15 Q. Well, I'm just asking you  
16 simply, would you acknowledge sitting here  
17 now -- I'll ask it differently.  
18 Do you wish when Jinsheng Lin  
19 sent this e-mail in July of 2017 that it  
20 hadn't been ignored and it didn't fall  
21 through the cracks, and that your company had  
22 taken immediate action to stop manufacturing  
23 valsartan with sodium nitrite quenching?  
24 MR. GALLAGHER: Objection.

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1 Vague, calls for speculation, and  
2 outside the scope.  
3 A. I mean, at a time of point, if  
4 someone went through, you know, and if they  
5 are like process, you know, people, they  
6 probably, you know, as I said, you know, just  
7 saw him, you know, just making unrealistic  
8 projections. That's my guess. That's my  
9 guess.  
10 BY MR. SLATER:  
11 Q. Well, you're calling it an  
12 unrealistic projection. In fact, he was  
13 100 percent right.  
14 A. No, he is not 100 percent  
15 right. As I said, you know, he's making, you  
16 know, those things -- as I said, you know,  
17 not everything -- by now we know not every  
18 nitrosamine is highly toxic, okay?  
19 Like impurity K, based upon,  
20 you know, everything that we now know, you  
21 know, it has been controlled but treated as a  
22 regular impurity at 1,000 ppm, you know, that  
23 was by Novartis, the original inventor of  
24 valsartan.

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1 Q. You're certainly not telling me  
2 that valsartan with NDMA is acceptable to be  
3 sold with 1,000 ppm.  
4 You're not saying that, are  
5 you?  
6 A. I'm saying --  
7 MR. GALLAGHER: Objection.  
8 Mischaracterizes.  
9 THE WITNESS: I'm sorry again.  
10 I'm saying since the beginning  
11 impurity K, which is also a  
12 nitrosamine compound, okay, right, the  
13 impurity K has been allowed by  
14 Novartis as well as by regulatory  
15 agencies, okay, at 1,000 ppm since the  
16 very beginning.  
17 BY MR. SLATER:  
18 Q. Didn't we establish a little  
19 earlier that you don't know what the FDA  
20 decision was with regard to impurity K?  
21 A. I told you that --  
22 MR. GALLAGHER: Objection.  
23 Outside the scope, asked and answered.  
24 A. I told you I don't know what's

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1 the current FDA position. But I told you,  
2 you know, based upon a European regulatory  
3 agency's, you know, a document, right, after,  
4 you know, these events, they specifically  
5 discussed, you know, impurity K.  
6 So based upon the knowledge  
7 from there, you know, that's how we came to  
8 know the impurity K has been, you know, at  
9 least, you know, towards that point, being  
10 controlled by Novartis at 1,000 ppm.  
11 BY MR. SLATER:  
12 Q. Okay. I'm asking about NDMA  
13 now. You understand that, right?  
14 A. If you want to talk, yeah, we  
15 can talk now.  
16 Q. It would never be acceptable to  
17 sell valsartan contaminated with NDMA, right?  
18 That would never be acceptable, right?  
19 MR. GALLAGHER: Objection.  
20 Vague, outside the scope, and calls  
21 for speculation.  
22 A. You know, I'm not a  
23 toxicologist, okay? So if you really want me  
24 to answer this question, I may give you my

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1 personal, you know, limited understanding by  
2 going through, you know, you know, the  
3 documents released by FDA particularly, some  
4 very recent, you know, training documents by  
5 FDA, right?  
6 So, I mean, for a reliable  
7 intake on the specification for NDMA, even  
8 from the perspective of FDA, they have  
9 changed quite a bit, okay?  
10 At the very beginning after,  
11 you know, you know, these events, FDA's  
12 position for NDMA was it should be absent.  
13 Okay. So basically, you know, you know, the  
14 specification would be defined by the limit  
15 of detection of a particular, you know,  
16 analytical method.  
17 But then, you know, after I  
18 don't know how long, maybe about a year or  
19 so, FDA, you know, then said that, you know,  
20 after all of the understanding, you know, of  
21 the new knowledge, you know, now they allow,  
22 you know, it to be present like 96 nanogram  
23 per day, right, for, you know, valsartan.  
24 And also if you look through

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1 some of the most recent training, FDA's, you  
2 know, like training, you know, you know, you  
3 know, training slides, it -- you know, you  
4 know, it mentioned that, you know, as I said  
5 earlier, you know, endogenously formed NDMA  
6 could be, you know, anywhere from 1,000 to  
7 more than 2,000 microgram per day. So this  
8 is, you know, extremely high. I mean...  
9 So basically, you know, without  
10 taking any medication, anyone will have that  
11 much of NDMA in you and me and everybody  
12 else's body, okay, 1,000 to more than 2,000  
13 microgram per day. This is from the official  
14 FDA's, you know, you know, training  
15 documents.  
16 So basically our understanding  
17 with regard to, you know, you know, the  
18 potential toxicity of NDMA, it looks like  
19 it's still progressing.  
20 BY MR. SLATER:  
21 Q. The FDA is not permitting ZHP  
22 to sell valsartan with NDMA impurity in the  
23 United States even up until the present day,  
24 correct?

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1 MR. GALLAGHER: Objection.  
2 Outside of the scope.  
3 BY MR. SLATER:  
4 Q. Correct statement, right?  
5 A. At this point, you know, the  
6 import ban is still there, but there's a lot  
7 of reasons. I think partly because of the  
8 pandemic.  
9 We had a meeting with FDA, I  
10 think at the end of 2019. During that  
11 meeting, you know, FDA has pretty much, you  
12 know, accepted our explanation, our  
13 responses, and the consensus was they would  
14 come over early 2020 to come over on site to  
15 do like, you know, a follow-up inspection.  
16 Q. The fact stands that from the  
17 time the FDA learned about NDMA in valsartan,  
18 they told ZHP to stop selling it and recall  
19 it, right?  
20 A. The only --  
21 MR. GALLAGHER: Objection.  
22 Outside the scope, and  
23 mischaracterizes, lack of foundation.  
24 Go ahead.

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1 THE WITNESS: Yeah, sorry.  
 2 Yeah.  
 3 I mean, only after certain  
 4 period, you know, of the  
 5 investigation, you know, and then, you  
 6 know, FDA had the warning letter and  
 7 also the import ban.  
 8 And, you know, once we  
 9 confirmed, you know, the presence of  
 10 NDMA, you know, in valsartan, we  
 11 reported it to the FDA, and we give  
 12 FDA our methods, and also we give FDA  
 13 our testing results, right, only like  
 14 maybe like two, three weeks, you know,  
 15 after June 6th.  
 16 And we had been talking to FDA,  
 17 asking for their guidance as to what  
 18 we should do, right? Whether we  
 19 should -- to do the recall, you know,  
 20 immediately or whatever.  
 21 But, you know, I think, you  
 22 know, during some of the early  
 23 response from FDA, you know, FDA still  
 24 at the time wasn't sure how to -- you

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1 know, how to move forward. They  
 2 specifically asked us to hold on, you  
 3 know, you know, to any recall, you  
 4 know, that we would like to do.  
 5 BY MR. SLATER:  
 6 Q. You spoke to the FDA, right?  
 7 A. Yeah, yeah. I was in the  
 8 meeting with FDA, yeah, at the end of, you  
 9 know, 2019, yes.  
 10 Q. Did you tell the FDA that your  
 11 company knew going back to at least July of  
 12 2017 and likely earlier, that you knew that  
 13 NDMA was occurring in valsartan due to the  
 14 quenching with sodium nitrite?  
 15 Did you tell that to the FDA?  
 16 A. I didn't have that knowledge,  
 17 as I said. Although, you know, it looks like  
 18 I was on the e-mail. But, as I said, I, you  
 19 know --  
 20 Q. Did anybody tell that to the  
 21 FDA from your company in 2018 or 2019 or 2020  
 22 or 2021?  
 23 MR. GALLAGHER: Objection.  
 24 Outside the scope.

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1 To the extent you know, Dr. Li,  
 2 you can answer.  
 3 A. Yeah, to the extent -- probably  
 4 not, to the extent that I know.  
 5 BY MR. SLATER:  
 6 Q. Well, speaking for ZHP  
 7 regarding the root cause investigation, as  
 8 part of that interaction with the FDA on your  
 9 root cause investigation, did you tell the  
 10 FDA that you had knowledge going back to 2017  
 11 and likely earlier that quenching the  
 12 valsartan with sodium nitrite was creating  
 13 NDMA?  
 14 Did you tell the FDA that?  
 15 A. As I said --  
 16 MR. GALLAGHER: Hang on,  
 17 Dr. Li. Sorry. Just pause for a  
 18 minute after the question to give me a  
 19 chance to object.  
 20 So objection, outside the  
 21 scope.  
 22 The topic number 2 is the root  
 23 cause investigation for nitrosamine  
 24 impurities, including NDMA and NDEA in

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1 the ZHP API, as we've discussed that,  
 2 and you have other topics about  
 3 regulatory issues and discussions with  
 4 FDA that's not within the topics for  
 5 today. So outside the scope.  
 6 Dr. Li, to the extent you know  
 7 personally, you can answer.  
 8 MR. SLATER: I'll ask the  
 9 question again.  
 10 BY MR. SLATER:  
 11 Q. As part of ZHP's root cause  
 12 investigation, did ZHP share with the FDA  
 13 that ZHP knew going back to at least  
 14 July 2017 and likely earlier that the  
 15 quenching of the valsartan with sodium  
 16 nitrite was the cause of the creation of  
 17 NDMA?  
 18 MR. GALLAGHER: Objection.  
 19 Outside the scope.  
 20 To the extent you know  
 21 personally, you can answer, Dr. Li.  
 22 A. I think I already, you know,  
 23 answered that question.  
 24 ///



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1 BY MR. SLATER:  
 2 Q. The answer is no, nobody told  
 3 the FDA, right?  
 4 A. As far as I aware.  
 5 MR. SLATER: Cheryll, let's  
 6 take this down and go, if we could --  
 7 see how quick you are -- to  
 8 Exhibit 208, which is the FDA Draft  
 9 Guidance from December 2008.  
 10 MS. CALDERON: It will take me  
 11 a minute.  
 12 MR. SLATER: I thought you were  
 13 going to pull it up and say you read  
 14 my mind.  
 15 Q. Let me ask you this while  
 16 Cheryll is looking for the document.  
 17 MR. SLATER: You can leave this  
 18 e-mail up for a moment, Cheryll.  
 19 Q. Did ZHP ever share this  
 20 July 27, 2017 e-mail with the FDA?  
 21 MR. GALLAGHER: Objection.  
 22 Outside the scope.  
 23 Dr. Li, to the extent you know  
 24 personally, you can answer.

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1 A. I don't know personally.  
 2 BY MR. SLATER:  
 3 Q. Did you tell the FDA, as part  
 4 of your interactions with them when they were  
 5 trying to learn the root cause of what had  
 6 happened, that you had directed people in  
 7 your department to cease work on a report  
 8 that was being prepared regarding the  
 9 creation of nitroso compounds due to sodium  
 10 nitrite quenching because of the sensitivity  
 11 of the impurity?  
 12 Did you tell that to the FDA?  
 13 MR. GALLAGHER: Objection.  
 14 Outside the scope, mischaracterizes  
 15 testimony and documents.  
 16 A. I didn't ask them to seize --  
 17 you know, to seize the work. The work has  
 18 already been done, right.  
 19 BY MR. SLATER:  
 20 Q. Well, do you think the FDA  
 21 would like to see that e-mail now? Do you  
 22 think they'd be interested in it?  
 23 MR. GALLAGHER: Objection.  
 24 Outside the scope, calls for

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1 speculation.  
 2 BY MR. SLATER:  
 3 Q. You've interacted with the FDA,  
 4 you know the interest they have in this  
 5 nitrosamine impurity issue. Do you think  
 6 they'd like to see the e-mail now?  
 7 MR. GALLAGHER: Objection.  
 8 Still calls for speculation.  
 9 A. I don't know.  
 10 BY MR. SLATER:  
 11 Q. We've put up on the screen  
 12 Exhibit 208, the FDA "Guidance for Industry"  
 13 regarding "Genotoxic and Carcinogenic  
 14 Impurities in Drug Substances and Products,"  
 15 with the "Recommended Approaches."  
 16 And this is FDA guidance.  
 17 You're familiar with this document, aren't  
 18 you?  
 19 A. I read through it before.  
 20 MR. SLATER: And let's go to  
 21 page 8, please, Cheryll, the top  
 22 carryover paragraph, please. You got  
 23 it. I just want the top -- the top of  
 24 the page. Scroll up. Yes. Perfect.

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1 Q. Looking at the --  
 2 MR. SLATER: Can you scroll up  
 3 more? Because it's confusing,  
 4 actually. No, the other way. Yes.  
 5 All right. Perfect.  
 6 Q. Looking at the carryover  
 7 paragraph on page 8, they're talking about  
 8 the threshold approach. And you've been  
 9 talking about threshold during this  
 10 deposition, correct?  
 11 A. We had some discussion, yeah,  
 12 about the specification, yeah.  
 13 Q. And as of 2008, looking at the  
 14 last sentence in that carryover paragraph on  
 15 page 8, it says, "However, there are some  
 16 compounds containing certain structural  
 17 groups, (aflatoxin-like-, N-nitroso- and  
 18 azoxy-structures) that have extremely high  
 19 carcinogenic potency and are excluded from  
 20 the threshold approach."  
 21 Do you see what I just read?  
 22 A. Mm-hmm.  
 23 Q. In terms of the knowledge of  
 24 the health risks and what's acceptable, your



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1 company, ZHP, absolutely knew this after it  
2 came out in 2008, right?

3 MR. GALLAGHER: Objection.  
4 Outside the scope, and lacks  
5 foundation.

6 A. That was before my joining the  
7 company. I had no specific knowledge, but my  
8 guess, it should be -- somebody should have  
9 read through this document.

10 BY MR. SLATER:  
11 Q. Certainly.  
12 And in the context of Topic 36,  
13 which was ZHP's evaluation and knowledge of  
14 the health risks of nitrosamines, this is  
15 important information saying that N-nitroso  
16 structures "have extremely high carcinogenic  
17 potency and are excluded from the threshold  
18 approach."

19 That's an important piece of  
20 information, correct?

21 MR. GALLAGHER: Objection.  
22 Vague.

23 A. That's what it state in this  
24 document. Okay.

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1 But also, you know, I think in  
2 this document, or maybe in a more updated,  
3 you know, M7, it also said, you know, you  
4 know, these approach usually are very  
5 conservative.

6 BY MR. SLATER:  
7 Q. Well, M7 says that "Some  
8 structural groups were identified to be of  
9 such high potency that intakes even below the  
10 threshold of toxicological concern would  
11 theoretically be associated with a potential  
12 for a significant carcinogenic risk. This  
13 group of high potency mutagenic carcinogens,"  
14 referred to as the "cohort of concern,"  
15 "comprises aflatoxin-like-, N-nitroso-, and  
16 azoxy compounds."

17 You know that's what M7 says,  
18 right?

19 A. Yes. But also it said  
20 potential, yeah.

21 Q. The point is this. The  
22 regulators around the world have determined  
23 that with the N-nitroso compounds, the risk  
24 of causing cancer to humans is too high to

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1 allow that to be in these drug substances,  
2 correct?

3 That's the decision that's been  
4 made around the world, correct?

5 MR. GALLAGHER: Objection.  
6 Outside the scope, calls for  
7 speculation, and calls for expert  
8 testimony.

9 A. As I said, you know, based upon  
10 some recently released material, training  
11 material by FDA, I think, you know, the  
12 potential risk -- our knowledge of the  
13 potential risk is still evolving, okay.

14 And also, as I said, some of  
15 the N-nitroso compounds, they are not  
16 genotoxic, okay, like impurity K.

17 But anything else, you know, I  
18 think it will up to, you know, a professional  
19 toxicologist, you know, to do further  
20 evaluation.

21 BY MR. SLATER:  
22 Q. In terms of ZHP's evaluation  
23 and knowledge of the health risks of  
24 nitrosamines, you would certainly agree with

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1 me that with regard to NDMA and NDEA, the  
2 nitrosamines at issue in this litigation,  
3 they're considered to be high potency  
4 mutagenic carcinogens, correct?

5 A. They're considered to be --  
6 well, those are the data based upon animal  
7 studies, okay. They are considered as  
8 potential or probable carcinogenic to humans,  
9 so this has not been fully confirmed.

10 Q. Based on the studies that have  
11 been performed, they're considered to be  
12 probable high potency mutagenic carcinogens.  
13 That's the considered wisdom at present,  
14 correct?

15 MR. GALLAGHER: Objection.  
16 Vague.

17 A. As I said, you know, the common  
18 consensus based upon FDA's release document  
19 or European, you know, regulators, yeah, NDMA  
20 or NDEA, they are potential or probable, you  
21 know, carcinogen to human.

22 BY MR. SLATER:  
23 Q. The word is "probable."  
24 They're considered probable, correct?

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1 A. Probable, you know, which means  
 2 it's not confirmed. It's not fully  
 3 confirmed.  
 4 Q. You're a scientist. "Probable"  
 5 means more likely than not, right?  
 6 A. Probably is probable, whatever  
 7 that -- you know, yeah, we can look at the  
 8 dictionary, yeah, probable, yeah.  
 9 But, again, probable, you know,  
 10 you know, again, is not a sure thing. I  
 11 mean, probable, you know, a lot of things  
 12 could be probable but eventually didn't  
 13 happen.  
 14 Q. You mentioned the word --  
 15 rephrase.  
 16 You used the word a moment ago  
 17 "consensus." The consensus among those  
 18 people who are responsible for this issue is  
 19 NDMA and NDEA are probable human carcinogens,  
 20 and they shouldn't be in drug substances for  
 21 that reason, because it's considered to be  
 22 too high a risk for humans, correct?  
 23 MR. GALLAGHER: Objection.  
 24 Vague --

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1 BY MR. SLATER:  
 2 Q. That's the consensus, right?  
 3 MR. GALLAGHER: Objection.  
 4 Vague, calls for speculation, and  
 5 expert testimony.  
 6 A. Your question is not accurate.  
 7 You know, and I think I answered that  
 8 question before, okay?  
 9 You know, based upon, you know,  
 10 the current, you know, consensus, at least  
 11 from FDA, okay, you know, based upon your  
 12 process, I mean, obviously the best way would  
 13 be to avoid. But we know, you know, for  
 14 the -- you know, for the -- you know, for the  
 15 valsartan, you know, you know, process  
 16 chemistry, it looks like, you know, you just  
 17 cannot avoid, you know, the formation.  
 18 So it's a certain level of NDMA  
 19 would be allowed, okay. So, as I said, right  
 20 now the consensus is 96 nanogram per day,  
 21 okay. That's considered to be lifetime, you  
 22 know, you know, allowable intake level.  
 23 BY MR. SLATER:  
 24 Q. The levels of NDMA in ZHP's

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1 valsartan far exceeded that level, correct?  
 2 A. Based upon the current  
 3 knowledge, yes.  
 4 Q. The levels of NDMA in ZHP's  
 5 valsartan are considered to be unacceptable  
 6 for human consumption, right?  
 7 MR. GALLAGHER: Objection.  
 8 Vague.  
 9 A. That's retrospective. That's  
 10 based upon today's knowledge, okay. This may  
 11 change over time, you know, either be  
 12 tightened or even maybe be loosened, okay,  
 13 because the reason, again, you know, based  
 14 upon FDA release the training document, you  
 15 know, they endogenously formed NDMA, right?  
 16 As I said, you know, anybody  
 17 like you and me, you know, just by, you know,  
 18 changing the normal food, the NDMA then will  
 19 be formed because of just simply by taking  
 20 the food, it will be produced anywhere  
 21 between 1,000 microgram to 2,000 -- you know,  
 22 more than 2,000 microgram per day.  
 23 Q. What are you quoting for those  
 24 numbers?

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1 A. Those are from the recent FDA  
 2 trainings, you know, you know, document. I  
 3 think, you know, my counsel can send these  
 4 documents to you. I mean, these are, you  
 5 know, publicly available information.  
 6 Q. Are you telling us that because  
 7 certain nitrosamines can form at very low  
 8 levels in nature, that it's acceptable that  
 9 ZHP was selling valsartan --  
 10 (Over-speaking.)  
 11 A. No, no, no. Don't twist.  
 12 Q. Are you saying that or not?  
 13 A. No, I'm not saying that. I'm  
 14 just saying the fact, okay? I'm not  
 15 saying -- okay. What I'm telling you is  
 16 several facts, okay, right?  
 17 First of all, you know,  
 18 FDA's -- after the events, right, FDA's --  
 19 first of all, you know, at the time, you  
 20 know, nobody knew, you know, you know,  
 21 immediately what the -- you know, a limit or  
 22 an interim limit should be, right?  
 23 And then so after some time,  
 24 you know, the interim limit was established,

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1 okay? The interim limits was 96 nanogram per  
2 day, okay.  
3 And then, you know, after some  
4 time FDA's position was that NDMA, also NDEA,  
5 should be absent, right?  
6 And then more recently, you  
7 know, they loosened the standard, okay,  
8 they -- you know, the NDMA now, you know,  
9 being allowed, you know, to a maximum level  
10 96 nanogram per day, right?  
11 So -- but in the training,  
12 FDA's training material, you know, you know,  
13 they had those things, you know, they had,  
14 you know, those discussions.  
15 So, yeah, so based upon that,  
16 you know, you know, you know, you know, the  
17 material -- okay, also based upon the  
18 principle of M7, right?  
19 And that's a reasonable  
20 speculation that, you know, FDA or  
21 somebody -- you know, other regulator they  
22 may, you know, change the acceptable limits  
23 in the future, okay?  
24 You know, because if you look

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1 at the -- you know, the M7, right, it says if  
2 data, you know, potential genotox impurity,  
3 if they -- you know, if they come, you know,  
4 if the source for another source, right,  
5 other than a medication is more than, you  
6 know, what you can take from a medical  
7 product, you know, then -- you know, then in  
8 general, you know, you know, their level, you  
9 know, may be -- you know, may be loosened,  
10 okay, based upon, you know, that fact.  
11 Q. The levels of NDMA in ZHP's  
12 valsartan would never have been acceptable in  
13 2014, 2015, 2016, 2017, or 2018?  
14 MR. GALLAGHER: Objection.  
15 Vague, compound.  
16 BY MR. SLATER:  
17 Q. Do you agree with me those  
18 levels were so high, they never would have  
19 been acceptable in any of those years,  
20 correct?  
21 MR. GALLAGHER: Objection.  
22 Vague, compound, calls for  
23 speculation, and expert testimony.  
24 A. You know, retrospectively, you

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1 know, that would be the case. But don't  
2 forget, you know, we have the -- you know, we  
3 didn't have that specification. And all the,  
4 you know, all the specification that we  
5 tested, you know, and released upon, they  
6 have been submitted and also approved by  
7 regulatory agencies, including FDA.  
8 BY MR. SLATER:  
9 Q. Well, you're certainly not  
10 telling me that ZHP and yourself, who joined  
11 the company in 2014, could have thought that  
12 the levels of NDMA in your valsartan would  
13 have been acceptable back in 2014 or 2015 or  
14 2016 or 2017 or 2018?  
15 You're not telling me that ZHP  
16 would have thought these levels would have  
17 been acceptable, are you?  
18 MR. GALLAGHER: Objection.  
19 A. As I said --  
20 MR. GALLAGHER: Wait, hang on.  
21 Objection. Vague, compound,  
22 calls for speculation, expert  
23 testimony, and asked and answered.  
24 ///

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1 BY MR. SLATER:  
2 Q. At that time, you didn't need  
3 to say it's retrospective. In 2015, for  
4 example, I'm looking at the levels on the  
5 documents submitted to the FDA. You had  
6 levels of over 100 parts per million in some  
7 batches.  
8 You could never have thought  
9 that was acceptable to sell under any  
10 circumstances at that time, right?  
11 MR. GALLAGHER: Objection.  
12 Vague, calls for expert testimony,  
13 argumentative, and lacks foundation.  
14 A. Again, with a specific level,  
15 you know, this is outside of my expertise.  
16 As I said, this up to toxicologists, also  
17 regulators, you know, finally, you know, you  
18 know, their job to determine.  
19 BY MR. SLATER:  
20 Q. Validation batch number 1,  
21 batch number C5355-12-003 manufactured on  
22 December 28, 2011 was tested by your company  
23 at NDMA level of 76 parts per million.  
24 That level, your company never

<p style="text-align: right;">Page 194</p> <p>1 would have thought was acceptable for sale at                  2 any point during the entire time valsartan                  3 was sold, correct?                  4 MR. GALLAGHER: Objection.                  5 Outside the scope, vague, calls for                  6 speculation, and expert testimony.                  7 THE WITNESS: I don't know, do                  8 I need to answer the question?                  9 MR. GALLAGHER: Yes. To the                  10 extent you know, you should answer.                  11 A. I mean, basically, as I said,                  12 you know, retrospectively, you know, you                  13 know, those levels are above the current,                  14 okay, established limit.                  15 BY MR. SLATER:                  16 Q. Those levels were so high that                  17 if your company had actually acknowledged to                  18 the outside world that NDMA was forming due                  19 to the sodium nitrite quenching, you know,                  20 and you can agree with me right now, your                  21 sale of valsartan would have been shut down                  22 immediately as soon as your company disclosed                  23 that, correct?                  24 MR. GALLAGHER: Objection.</p>	<p style="text-align: right;">Page 196</p> <p>1 MR. GALLAGHER: Okay.                  2 BY MR. SLATER:                  3 Q. The FDA never indicated that                  4 the NDMA levels in the valsartan sold by your                  5 company were acceptable. All they said is                  6 they had to figure out how much supply was                  7 out there due to the extent of the                  8 contamination of your pills, and they had to                  9 just make sure that there was enough                  10 medication out there for people's blood                  11 pressure to be controlled for a short period                  12 of time.                  13 That's all the FDA let you do,                  14 right?                  15 MR. GALLAGHER: Objection.                  16 Outside the scope, and lacks                  17 foundation.                  18 A. I don't know, you know, because                  19 I'm not the person, you know, to be directly                  20 involved with the -- you know, with the                  21 recall.                  22 So I don't -- you know, I don't                  23 know exactly, you know, what you, you know,                  24 just said to me, okay, but, you know,</p>
<p style="text-align: right;">Page 195</p> <p>1 Argumentative, calls for speculation,                  2 and expert testimony.                  3 A. That's not the case, okay. As                  4 I told you, once we -- you know, after -- you                  5 know, after that particular event, after we                  6 have got, you know, those data, right, from                  7 the initial, like, 50 batches or so, we                  8 reported, you know, like up to two, three                  9 weeks roughly, we reported it to the FDA.                  10 We asked them their guidance,                  11 okay, and we mentioned, I think, you know, at                  12 least in one of the communications whether we                  13 should do the recall. And they specifically                  14 told us to be hold on.                  15 So this is not what you're                  16 saying, you know, you know, all right?                  17 So, essentially, it need to be                  18 evaluated by, you know, experts.                  19 MR. GALLAGHER: Adam, we've                  20 been going almost an hour and                  21 20 minutes.                  22 MR. SLATER: I just have a                  23 couple quick follow-up questions, and                  24 then we can take a break.</p>	<p style="text-align: right;">Page 197</p> <p>1 assuming that's true, so at least, you know,                  2 what that indicate, you know, there is no,                  3 you know, immediate, you know, you know -- I                  4 mean, it still be tolerable considered, you                  5 know, that particular medical need.                  6 And again, you know, you know,                  7 the level, like you said, 70-some ppm, is                  8 not, you know -- you have saying, you know,                  9 you know, you know, consider, for example,                  10 like ranitidine, right?                  11 If you look at ranitidine,                  12 okay, this is a compound or is a medication                  13 developed by, you know, GSK or its precursor,                  14 you know, company, like SmithKline, like                  15 about 40 years ago, okay?                  16 And now we know that, you know,                  17 you know, the level, you know, you know, of                  18 this, you know, probably -- I think the                  19 actual level was like 47 micrograms or                  20 something.                  21 So, yes, so that's, you know,                  22 higher than I think our, you know, you know,                  23 NDMA, you know, in those batches.                  24 MR. SLATER: I think that we</p>

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1 can take a break off of the ranitidine  
2 testimony and take a break, so we can  
3 go off the record.  
4 THE VIDEOGRAPHER: The time  
5 right now is 11:01 a.m. We're now off  
6 the record.  
7 (Whereupon, a recess was  
8 taken.)  
9 THE VIDEOGRAPHER: The time  
10 right now is 11:16 a.m. We're back on  
11 the record.  
12 BY MR. SLATER:  
13 Q. We're looking at Exhibit 284,  
14 and this is an e-mail sent by some people at  
15 Novartis to ZHP on May 22, 2018.  
16 Do you see that?  
17 A. Yeah, it looks like, yeah.  
18 Mm-hmm.  
19 Q. And the e-mail says, "Dear  
20 Huahai colleagues, During our analysis of  
21 residual solvents by GC (using a combined  
22 method) at Novartis we have found a number of  
23 solvents that we cannot identify for the  
24 following batches. The peak areas vary

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1 depending on the batch. These are the  
2 batches analyzed."  
3 And they give the list of the  
4 batches, right?  
5 A. It looks like, mm-hmm.  
6 Q. And ultimately they also attach  
7 their gas chromatography method for ZHP to  
8 review and ask, "I would appreciate your  
9 support on this and feel free to call me if  
10 any further information is required."  
11 So they were asking ZHP, what  
12 are these unknown peaks in these various  
13 batches of valsartan API, correct?  
14 A. Yes, mm-hmm.  
15 Q. And we know in retrospect, as  
16 you've said earlier, that gas  
17 chromatography-mass spectrometry, if focused  
18 at that time, would show NDMA, correct?  
19 MR. GALLAGHER: Objection.  
20 Mischaracterizes testimony.  
21 A. No, I didn't.  
22 BY MR. SLATER:  
23 Q. Well, let's go further then.  
24 Let's go now to Exhibit 288.

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1 And this is June 5, 2008 --  
2 rephrase.  
3 Looking now at Exhibit 288,  
4 this is a June 5, 2018 e-mail, again from  
5 Novartis to multiple people in your company,  
6 including yourself, correct?  
7 A. Let me see whether -- am I on  
8 it? Let me --  
9 Q. Second-to-last line of the CC  
10 list.  
11 A. Oh, yes, mm-hmm. Yeah.  
12 Q. You're there, and just above  
13 you is Peng Dong.  
14 Do you see that?  
15 A. Yes, mm-hmm. I saw him, yes.  
16 Q. Two of the people who received  
17 that July 2017 e-mail we've gone through from  
18 Jinsheng Lin, correct?  
19 A. Yes, mm-hmm.  
20 Q. And at this point now Novartis  
21 advises you that "We have done some tests in  
22 Solvias labs for Novartis of three batches of  
23 Huahai material and have a tentative  
24 assessment."

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1 And they then point out that  
2 they're asking for your company to assess  
3 this and comment as soon as possible, right?  
4 A. Yeah, looks like, mm-hmm.  
5 MR. SLATER: And as we flip  
6 through, Cheryll, if could you go  
7 forward to the page that says 798,  
8 with regard to the first batch that  
9 was tested.  
10 Q. Do you see there that there's  
11 identification of NDMA, and it says  
12 "tentative," correct?  
13 A. Yes.  
14 Q. And you're familiar with this  
15 document, right? So you know that for the  
16 next two batches, the same finding was made,  
17 right?  
18 A. Mm-hmm.  
19 Q. And the NDMA in the valsartan  
20 is what was discussed by Jinsheng Ling in the  
21 July 2017 e-mail, correct?  
22 A. He was not specifically at the  
23 time talking about this particular peak. He  
24 just -- at that time he was making, you know,



<p style="text-align: right;">Page 202</p> <p>1 you know, a guess.</p> <p>2 Q. He was -- well, he -- rephrase.</p> <p>3 He said that NDMA occurs in</p> <p>4 valsartan when quenched with sodium nitrite,</p> <p>5 and this here in June of 2018 is Novartis</p> <p>6 bringing to your attention that they</p> <p>7 tentatively think they've identified a peak</p> <p>8 that shows NDMA in valsartan, correct?</p> <p>9 A. Yes.</p> <p>10 Q. At any point in the</p> <p>11 communications with Novartis, did you or</p> <p>12 anybody else from ZHP tell Novartis that your</p> <p>13 company knew at least as of July 2017 that</p> <p>14 NDMA was forming in the valsartan that was</p> <p>15 quenched with sodium nitrite?</p> <p>16 Did you tell Novartis about</p> <p>17 that?</p> <p>18 A. I don't remember what we</p> <p>19 responded. I mean, can you go down to the --</p> <p>20 or go through the whole e-mail?</p> <p>21 Q. Well, this is the e-mail.</p> <p>22 There's no response to it. That's the</p> <p>23 e-mail. You're seeing at the top of the</p> <p>24 first page --</p>	<p style="text-align: right;">Page 204</p> <p>1 shows that that was disclosed, right?</p> <p>2 A. Not as far as I know.</p> <p>3 Q. Let's now go to Exhibit 289,</p> <p>4 which is the report from Solvias that was</p> <p>5 provided with the June 5, 2018, e-mail.</p> <p>6 You've seen this report,</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 MR. SLATER: And let's go now</p> <p>10 to the second page of this document</p> <p>11 where the objective is listed.</p> <p>12 Perfect.</p> <p>13 Q. And the objective of this study</p> <p>14 was as follows. "Unknown compounds were</p> <p>15 detected in the analysis of residue solvents</p> <p>16 in Valsartan, a product of Novartis</p> <p>17 International Pharmaceuticals." I'll stop</p> <p>18 there.</p> <p>19 And the reason it says that is</p> <p>20 because, as you know, Novartis had purchased</p> <p>21 this API from ZHP and then provided it to</p> <p>22 Solvias to test it, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And then this says, "Solvias</p>
<p style="text-align: right;">Page 203</p> <p>1 MR. SLATER: Cheryll, you can</p> <p>2 go back to the beginning.</p> <p>3 Q. -- that is the e-mail.</p> <p>4 A. That's the whole?</p> <p>5 Q. So my question is this.</p> <p>6 Did ZHP tell Novartis that ZHP</p> <p>7 knew at least as of July 2017 that there was</p> <p>8 NDMA in its valsartan? I just want to know</p> <p>9 if your company told that to Novartis.</p> <p>10 A. I don't remember. I don't</p> <p>11 know. I mean, I -- you know, I was not</p> <p>12 involved, you know, in most of those, you</p> <p>13 know, you know, e-mail communication. I</p> <p>14 was -- some of those e-mail communication,</p> <p>15 just telling them about some technical</p> <p>16 issues, I think.</p> <p>17 Q. Well -- rephrase.</p> <p>18 Have you seen anything</p> <p>19 indicating that ZHP disclosed to Novartis</p> <p>20 when Novartis came with its concerns about</p> <p>21 these unknown peaks that your company already</p> <p>22 knew that there was NDMA in the valsartan?</p> <p>23 A. I have no knowledge.</p> <p>24 Q. You haven't seen anything that</p>	<p style="text-align: right;">Page 205</p> <p>1 received the task from Novartis to analyse</p> <p>2 and identify the unknown compounds using</p> <p>3 Headspace GC/MS analysis."</p> <p>4 And I want to stop there and</p> <p>5 ask you, "GC/MS analysis" is gas</p> <p>6 chromatography-mass spectrometry, correct?</p> <p>7 A. Yes.</p> <p>8 Q. That's a technology that's been</p> <p>9 available -- as of 2018, for how long had</p> <p>10 that been available?</p> <p>11 A. It was quite long.</p> <p>12 Q. And then it says, "This report</p> <p>13 summarizes the results of this analysis."</p> <p>14 Correct?</p> <p>15 A. Mm-hmm.</p> <p>16 Q. And by the way, when you say</p> <p>17 that GC-MS was available for quite a long</p> <p>18 time, it certainly was available as of 2011</p> <p>19 when these processes were being developed by</p> <p>20 ZHP, correct?</p> <p>21 A. It was available as an</p> <p>22 instrument, you know, to the market.</p> <p>23 I just -- you know, you know,</p> <p>24 yesterday I just asked, you know, you know,</p>

<p style="text-align: right;">Page 206</p> <p>1 Mr., you know, Chen, you know, Wenbin Chen,                  2 you know, also on one of the e-mails, I ask                  3 him when we receive the first one.                  4 I think it was somewhere like                  5 in 2013, Huahai, or at least, you know, you                  6 know, that organization prior to my joining,                  7 you know, that technical, you know,                  8 supporting group, you know, was getting the                  9 first one somewhere in 2013, yes.                  10 Q. When you're testifying right                  11 now, are you testifying that you know that                  12 ZHP got its first GC-MS machine in 2013?                  13 A. Yes.                  14 Q. Are you sure they didn't have                  15 one earlier?                  16 A. Well, at least not in my                  17 organization, on my prior, you know,                  18 organization that I inherited.                  19 Yeah, they may have -- I don't                  20 know. I mean, like, you know, in the                  21 headquarters, you know, organizations, you                  22 know, like in Xunqiao, right, yeah, that was                  23 the first GC-MS that was there.                  24 Q. One of the things that a</p>	<p style="text-align: right;">Page 208</p> <p>1 withdraw the outside the scope                  2 objection.                  3 But it's vague, lacks                  4 foundation, and calls for speculation                  5 and expert testimony.                  6 BY MR. SLATER:                  7 Q. You know that, right, that it's                  8 been known for many years, going back at                  9 least to the 1970s, that GC-MS is the best                  10 method to identify nitrosamines, correct?                  11 MR. GALLAGHER: Same                  12 objections.                  13 A. I only know retrospectively                  14 people have done, you know, previously, but                  15 not, you know, with valsartan or any other                  16 sartans.                  17 And, you know, when you                  18 mentioned 1970s, I don't remember, you know,                  19 you know, the specific time frame.                  20 But again, GC-MS has been                  21 mostly, you know, more like a research tool                  22 for QC residual solvent method. GC-FID                  23 method remains to be, even as of today, you                  24 know, the choice of, you know, of the method</p>
<p style="text-align: right;">Page 207</p> <p>1 company like ZHP should do is make sure that                  2 it obtains the type of technology that's                  3 available for it to manufacture quality                  4 substances, correct?                  5 MR. GALLAGHER: Objection.                  6 Vague, and outside the scope.                  7 A. You know, the residual solvent                  8 method typically uses GC-FID technology,                  9 okay? So for those, you know -- so typically                  10 people will not do the GC-MS, you know, to                  11 develop a residual solvent method.                  12 BY MR. SLATER:                  13 Q. It's been known since the 1970s                  14 and going back that GC-MS is the best way to                  15 identify nitrosamines, correct?                  16 MR. GALLAGHER: Objection.                  17 Vague, lacks foundation, calls for                  18 speculation and expert testimony, and                  19 outside the scope.                  20 MR. SLATER: It's outside the                  21 scope of the chromatogram and mass                  22 spectrometry with --                  23 (Over-speaking.)                  24 MR. GALLAGHER: I would</p>	<p style="text-align: right;">Page 209</p> <p>1 for controlling residual solvents.                  2 MR. SLATER: Well, let's now go                  3 to page -- the Bates number is 13 in                  4 the bottom right. Keep going. Let's                  5 get the whole bottom half of the page                  6 in. Perfect. Thank you, Cheryl.                  7 BY MR. SLATER:                  8 Q. Looking now at Figure 2 in the                  9 Solvias report, it's a chromatogram of                  10 valsartan, and it has the batch number                  11 18-038M01, provided by Novartis to Solvias.                  12 Do you see that?                  13 A. Mm-hmm.                  14 Q. Can you tell what type of                  15 chromatogram that is?                  16 A. Yeah, it looks like a                  17 chromatogram from GC-MS analysis.                  18 Q. And if you look at it, it says                  19 that Table 4 -- rephrase.                  20 First of all, looking at the                  21 chromatogram itself -- actually, we'll come                  22 back to that. Looking at -- rephrase.                  23 Below the Figure 2, the                  24 chromatogram, it says in part, "Table 4</p>

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1 displays the corresponding retention times  
2 and calculated relative retention times."  
3 Do you see that?  
4 A. Mm-hmm. Okay.  
5 MR. SLATER: And if we scroll  
6 to the next page, and then we'll  
7 scroll back in a moment, but if we  
8 scroll to the next page -- perfect.  
9 Q. You see at number 18 toluene  
10 with a retention time of 10.46.  
11 Do you see that?  
12 A. Mm-hmm.  
13 Q. And then right below it, number  
14 19, it says "not applicable, 12.25."  
15 Do you see that?  
16 A. Mm-hmm.  
17 Q. And the "not applicable" there  
18 means it hasn't been identified, right?  
19 A. Probably.  
20 Q. And then if you scroll further  
21 down into the next table, 5, it says  
22 "Tentative identification of unknown peaks  
23 detected in Valsartan."  
24 MR. SLATER: Cheryll, if you

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1 scroll further, please.  
2 Q. 18 and 19 matching up again, at  
3 18 we have toluene, correct?  
4 A. Mm-hmm.  
5 Q. And 19, NDMA, and they call it  
6 "tentative," right?  
7 A. Right.  
8 Q. So based on this, if we go back  
9 now to the chromatogram at Figure 2, the  
10 toluene is that peak on the right, the taller  
11 peak third from the right. And I know that  
12 the writing is incredibly small. We can  
13 probably blow it up quite a bit.  
14 MR. SLATER: So let's do that.  
15 A. Sure.  
16 Q. I don't know if we can blow it  
17 up enough, but I can tell you --  
18 A. Okay.  
19 Q. -- that says toluene, 10.46.  
20 A. Okay. All right. Okay. This  
21 one. Okay.  
22 MR. SLATER: Good job, Cheryll.  
23 Q. And then the NDMA peak that  
24 they identified at 12.25 --

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1 MR. SLATER: If you scroll down  
2 a little further down, Cheryll.  
3 Perfect. And scroll to the right so  
4 we can see the peak to the right.  
5 Q. That next peak to the right of  
6 the toluene is 12.25.  
7 Do you see that?  
8 A. Yes, mm-hmm. Okay.  
9 Q. And to -- rephrase.  
10 And using your terminology, in  
11 retrospect and as proven -- well, rephrase.  
12 As proven here and as you  
13 subsequently confirmed, that's the NDMA peak,  
14 correct?  
15 A. I don't know, you know -- wait  
16 a second. I think on the table, you know,  
17 you know, it was their method. This is not  
18 NDMA. I think, you know, if I remember  
19 correctly just moments ago, the other way  
20 should be like, what, 15 something, or what?  
21 Can you go down the list?  
22 Q. Sure. And you can tell me  
23 which one is the NDMA peak. Why don't we do  
24 that.

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1 A. Well, you know, I'm not very  
2 familiar with Novartis', you know -- you  
3 know, all of those details, okay. Yeah,  
4 going down the other -- yeah.  
5 MR. SLATER: Go to the next  
6 table, Cheryll.  
7 A. Yeah, yeah, yeah, yeah, yeah.  
8 Because I don't think -- yeah, it shows the  
9 retention time like 15 something. 19.  
10 Yeah, 15 -- yeah, see that,  
11 yeah, 15 point -- almost 16 minutes. So it  
12 should not be that one immediately after, you  
13 know, the toluene with their method.  
14 Q. Well, in fact, if you look at  
15 the retention times for the two different  
16 tables, they're actually different, and the  
17 one that matches up to the chromatogram is  
18 the 10.46 and the 12.25.  
19 Do you know why those numbers  
20 are different?  
21 A. I don't know. I mean, it's  
22 their method.  
23 THE WITNESS: Can we go up,  
24 yeah, and take a look at toluene in

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1 the first table? Yeah. I mean, this  
2 one -- yeah.  
3 A. See where the toluene -- yeah,  
4 on the first table -- what's the retention  
5 time?  
6 Oh, hold on. I'm sorry. Okay.  
7 Okay. So -- okay. So, yeah, somehow, you  
8 know, the retention time, they're quite  
9 different. On this table toluene is like  
10 10.46, yeah.  
11 MR. SLATER: Let me see if we  
12 can -- go to the chromatogram, please,  
13 Cheryll. Just let's go to the  
14 picture.  
15 Q. Maybe we can find a common  
16 ground. What we do know is this. The  
17 toluene elutes, and then the NDMA elutes to  
18 the right of it, correct?  
19 A. No. Actually, if you're  
20 talking about, you know, ZHP's method, okay,  
21 what I can tell you the profile.  
22 Okay. Yeah. So we have the  
23 toluene and then we have the next, like,  
24 somewhat, you know, more obvious peak, like

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1 the one, you know, you just trying to point  
2 out to me like 12 point something, right?  
3 But I'm not saying our method, you know, they  
4 have this retention time, okay. I'm just  
5 talking about, you know, you know, the  
6 elution profile, okay?  
7 So after the first somewhat  
8 more obvious peak, after the toluene, based  
9 upon our, you know, analysis, it's not NDMA,  
10 okay? That, you know, that peak was n-butyl  
11 acetate, okay? And so based upon our  
12 analysis retrospectively, the NDMA eluting at  
13 the shoulder peak of the n-butyl acetate.  
14 Q. Okay. So -- rephrase.  
15 So the NDMA is to the right of  
16 the toluene, correct?  
17 A. It's right to the toluene, and  
18 also it's right to the first -- you know,  
19 yeah, right to the n-butyl acetate.  
20 Q. And on this test Solvias was  
21 able to tentatively identify the NDMA peak,  
22 correct?  
23 A. Based upon, yeah, their report,  
24 yes.

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1 Q. And let me -- explain -- tell  
2 me if I understand this correctly. If you do  
3 an appropriate risk assessment and know that  
4 NDMA potentially formed, and you used GC-MS  
5 and looked for NDMA, you can find it, right?  
6 MR. GALLAGHER: Objection.  
7 Vague and compound, and calls for  
8 speculation.  
9 A. I mean, retrospectively, if you  
10 want to specifically look for it using GC-MS  
11 or, you know, GC-MS/MS, yeah, you might be  
12 able to find it, yes.  
13 BY MR. SLATER:  
14 Q. And that's ultimately what  
15 happened, right? When ZHP was looking for it  
16 after Novartis came to you, you identified  
17 it, right?  
18 A. Yes.  
19 Q. And in fact, as we've talked  
20 about earlier in the deposition, we've now  
21 seen an e-mail showing that it was discussed  
22 within your company almost a year earlier,  
23 that your company already knew that NDMA was  
24 in the valsartan, correct?

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1 A. It's not, you know, ZHP knew.  
2 I mean, it was Mr. Lin, you know, he made  
3 that speculation.  
4 Q. He shared that information with  
5 you, Peng Dong, Linda Lin, Jucai Ge, people  
6 who had important positions in ZHP, right?  
7 MR. GALLAGHER: Objection.  
8 Vague.  
9 A. People who are employed by ZHP  
10 at the time, yes.  
11 BY MR. SLATER:  
12 Q. In important positions, in  
13 high-level positions, correct?  
14 MR. GALLAGHER: Objection.  
15 Vague.  
16 A. For some of them, I'm not sure.  
17 You know, it could be defined as high-level.  
18 For myself, yes, I'm at a high-level  
19 position, but not necessarily for every  
20 single one of them.  
21 BY MR. SLATER:  
22 Q. Peng Dong had a -- what about  
23 Peng Dong? What position was he in?  
24 A. He was -- probably at the time

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1 was a technical manager, so I would say this  
2 is a middle-level.  
3 Q. How about Jucai Ge?  
4 A. She was the QA. You know,  
5 she's a QA person, yeah. She's responsible,  
6 you know, for the QA department.  
7 Q. The QA is the quality assurance  
8 department, right?  
9 A. Right.  
10 Q. What does the quality assurance  
11 department do?  
12 A. They want to ensure, you know,  
13 product being manufactured according to, you  
14 know, predefined or particularly, you know,  
15 file the registrations for the regulatory  
16 authorities.  
17 Q. And Linda Lin was in the  
18 regulatory affairs department, correct?  
19 A. Yes.  
20 Q. She had a significant position,  
21 right?  
22 A. She's the head of the  
23 regulatory affairs.  
24 Q. And all of those people were

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1 put on notice at least as of July 2017 that  
2 there was NDMA in the valsartan, right?  
3 A. I mean, based upon that e-mail,  
4 I mean, you know, Mr. Lin made that e-mail.  
5 But again, you know, it looks like -- you  
6 know, it's just people maybe didn't go  
7 through or people maybe just saw that he's  
8 making, you know, exaggerations or...  
9 Q. But in reality he was right,  
10 and that's been proven, correct?  
11 MR. GALLAGHER: Objection.  
12 Asked and answered, and  
13 mischaracterizes the testimony.  
14 A. As I --  
15 I mean, do I need to answer?  
16 MR. GALLAGHER: You can answer.  
17 THE WITNESS: Okay.  
18 I mean, as I, you know,  
19 answered earlier, I mean, basically,  
20 you know -- you know, at that time,  
21 you know, you know, as I said, he was  
22 making his guess.  
23 But also, you know, the topic  
24 of the e-mail was talking about

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1 irbesartan, not -- you know, that  
2 particular irbesartan, you know,  
3 N-nitroso compound of the irbesartan,  
4 so it's not, you know, NDMA.  
5 BY MR. SLATER:  
6 Q. Well, you knew in April 2018  
7 that you didn't want that report that your  
8 department was working on to be completed or  
9 shown to anybody, and that's why you said --  
10 A. No. No, it's --  
11 Q. -- not to go further with that  
12 report, right?  
13 A. Well, see, I mean, you know,  
14 the -- you know, as I said, the work has  
15 already been -- you know, been done.  
16 You know, the reason, as I have  
17 explained, you know, I don't want to create a  
18 confusion, you know what I'm saying? And,  
19 you know, you know, was mixed up with, you  
20 know, those things.  
21 You know, because, you know,  
22 the topic of that document, you know, was  
23 about, you know, an impurity. That impurity  
24 was not even, you know, you know, you know,

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1 in a real impurity present in a commercial  
2 product.  
3 I mean, it was during, you  
4 know, the -- you know, the further -- or the  
5 trial, you know, in order to further, or  
6 trying to, you know, improve the quenching  
7 process of irbesartan.  
8 Q. And Mr. Lin, who was doing a  
9 very good job at the time, said, if this is a  
10 nitroso compound, we have a real problem  
11 here, similar to the problem we have with  
12 valsartan.  
13 He was doing a good job, and  
14 turned out in the end to have been the  
15 correct person, right?  
16 MR. GALLAGHER: Objection.  
17 Compound, mischaracterizes testimony,  
18 asked and answered.  
19 A. Again, you know, as I said, at  
20 least at that time or, you know, those guess  
21 or projection, you know, as I indicated to  
22 you, not all he said, you know, was correct,  
23 okay?  
24 Some he's making -- you know,



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1 he's, you know, guess, and he's also, you  
2 know, particularly with regard to, you know,  
3 the potential toxicity of the irbesartans,  
4 that particular N-nitroso derivative of  
5 irbesartan.  
6 You know, I don't think, you  
7 know, it was appropriate for him to make that  
8 judgment. You know, he is not a  
9 toxicologist.  
10 MR. SLATER: Cheryll, let's go  
11 to Exhibit 234, if we could, please,  
12 which is the other document that was  
13 provided in that Exhibit 288 to  
14 Novartis by ZHP.  
15 That is not the document I was  
16 expecting. I gave you the Bates  
17 number. It should be the "Study  
18 Report of Unknown Peak in Residual  
19 Solvent of Valsartan."  
20 THE WITNESS: Okay.  
21 MR. SLATER: I'm talking to  
22 Cheryll, though, but it's going to  
23 come to you in a moment.  
24 THE WITNESS: Okay.

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1 MR. SLATER: One second.  
2 Cheryll, what exhibit is this?  
3 MS. CALDERON: I have to check.  
4 Give me one second.  
5 MR. SLATER: I had 234 on it.  
6 I want to make sure we have it for the  
7 record.  
8 MS. CALDERON: I'm not sure. I  
9 have to look. It's not --  
10 MR. SLATER: I don't want to  
11 waste any more time with this, so  
12 let's just mark it again. What number  
13 are we up to?  
14 THE STENOGRAPHER: 305.  
15 (Whereupon, Exhibit Number  
16 ZHP-305 was marked for  
17 identification.)  
18 BY MR. SLATER:  
19 Q. Do you see what we've put up as  
20 Exhibit 305, "Study Report of Unknown Peak in  
21 Residual Solvent of Valsartan"?  
22 A. Mm-hmm.  
23 Q. You're familiar with this,  
24 correct?

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1 A. I went through this report,  
2 yes.  
3 Q. Okay. And if we turn to the  
4 next page, it's dated May 31, 2018, correct?  
5 Do you see that?  
6 A. Yes.  
7 Q. If we turn to the next page, it  
8 was actually signed off by several people,  
9 including --  
10 MR. SLATER: If you could turn  
11 to the next page, Cheryll. Thanks.  
12 Q. You see it was signed off by  
13 multiple people, including Peng Dong,  
14 correct?  
15 A. Mm-hmm.  
16 MR. SLATER: And now if we go  
17 to the next page, please. Let's go  
18 past the "Contents." I'm sorry.  
19 Let's go to the "Background" section,  
20 next page. So we're now on page 2 of  
21 23.  
22 Q. So there's a "Background"  
23 section of this report that talks about the  
24 fact that there were many unknown peaks

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1 identified with the residual solvent for  
2 valsartan with the Huahai method, correct?  
3 A. Yes, mm-hmm.  
4 Q. And just below that  
5 "Background" section there's Figure 1, which  
6 is titled as a "Typical chromatogram of  
7 Huahai method."  
8 Do you see that?  
9 A. Mm-hmm.  
10 Q. What does that mean, "typical  
11 chromatogram"?  
12 A. "Typical" usually means  
13 representative, which means, you know, it can  
14 be an example to illustrate.  
15 Q. And it says "FID." So is this  
16 a gas chromatography-FID test?  
17 A. Yes.  
18 Q. And you can see a little better  
19 on this -- rephrase.  
20 And you can see the peaks are  
21 labeled, and the peak that's labeled farthest  
22 to the right with a label is toluene.  
23 Do you see that?  
24 A. Yeah, mm-hmm.

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1 Q. And then there's a series of  
2 unidentified smaller peaks to the right of  
3 that?  
4 A. Yes.  
5 Q. And without figuring out which  
6 one it is or exactly where it is, we know in  
7 hindsight that the NDMA can be identified  
8 there if one looks for it with gas  
9 chromatography-mass spectrometry, correct?  
10 A. No, that's not correct.  
11 Q. If you were to be asked to go  
12 and use GC-MS to look for NDMA, you don't  
13 think you could identify it on this sample?  
14 A. GC-MS and GC-FID, they are two  
15 different, quite different methods.  
16 Q. No, let me ask the question  
17 differently, because that's not what I -- I  
18 get why you're saying that, though.  
19 If one decided to test by GC-MS  
20 instead of GC-FID, this batch, and actually  
21 looked for NDMA, it would be able to be  
22 identified with the GC-MS, correct?  
23 A. If you -- what we found out,  
24 okay, if you just use, you know -- you know,

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1 basically if you use the conditions, right,  
2 including the sample concentrations as in  
3 this GC-FID method, if you then turn that  
4 into a GC-MS method based upon our  
5 retrospective, you know, analysis, you will  
6 not be able to see NDMA, okay?  
7 And then I think that during  
8 this investigation, the concentration of the  
9 sample, you know, was increased by 20 times.  
10 And even that, with the GC-MS chromatogram,  
11 you know, you can see, you know, I think in  
12 some of the figures, you know, I think in  
13 some of the figures, you know, in this report  
14 the NDMA peak was still not very obvious. It  
15 was buried among other, you know, unknown  
16 peaks.  
17 Q. The other night Qiangming Li  
18 testified that the NDMA peak eluted on the  
19 GC-FID between 14.2 and 14.5.  
20 Does that sound correct to you?  
21 A. I don't know. I mean,  
22 because -- from --  
23 MR. GALLAGHER: Objection.  
24 THE WITNESS: Sorry.

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1 MR. GALLAGHER: Go ahead.  
2 A. You know, you know, I cannot  
3 confirm, you know, the specific time range,  
4 okay. But I can tell you, you know, just  
5 look at this, you know, you know, Figure 1,  
6 right.  
7 You know, basically after the  
8 toluene peak, you have like three, right,  
9 roughly three peaks, right? You see that?  
10 Three little peaks?  
11 Q. Yes.  
12 A. Right? Okay. As I, you know,  
13 communicate, you know, to you earlier, the  
14 first little peak appears to be -- okay,  
15 there are two folds, okay.  
16 In the blank injection, there  
17 was also a blank peak, okay, eluting at that  
18 region, okay.  
19 With the real sample, at least  
20 for some batches, okay, what we found is, you  
21 know, this peak was n-butyl acetate, okay,  
22 and then NDMA, you know, you know, it would  
23 elute at the shoulder, you know, you know,  
24 you know, of this peak. If you, you know,

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1 making a reference then of NDMA with high  
2 enough concentration, you know, it will, you  
3 know, show a peak at that region.  
4 But with the regular batch,  
5 basically, you know, the NDMA is just -- you  
6 know, sometimes, you know, it just co-elute,  
7 complete co-elute, sometimes may be a very  
8 tiny, you know, shoulder peak there.  
9 Q. Solvias found it, right?  
10 A. They were using a quite  
11 different, okay, method, okay. If you  
12 notice, you know, one of the, you know, major  
13 differences, they were using NMP as the  
14 sample. You know, this particular method,  
15 ZHP's method utilizing DMSO, okay.  
16 So when you use different  
17 sample diluents, you will have different  
18 background peaks, okay?  
19 So at that particular region,  
20 when they turned that -- their NMP method  
21 into the corresponding GC-MS method, and also  
22 because, you know, the -- because NMP, you  
23 know, is a higher-volume point as compared to  
24 DMSO, right? So we did a comparison of the

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1 two methods.

2 Their, you know, like

3 incubation temperature, I think it was like

4 at least 15 degrees Celsius higher, you know,

5 you know, than the ZHP's method.

6 So the bottom line is, you

7 know, their GC-MS method appears to be more

8 sensitive than ZHP's, you know, GC-MS method.

9 Q. The point is, the technology

10 and the methodology was clearly available to

11 identify the NDMA, correct?

12 A. Well, but first of all -- yes,

13 the answer is yes, but, see, the first -- you

14 know, you need to know what to look for,

15 right? Yeah.

16 Q. When you say "you need to know

17 what to look for," you're talking about a

18 risk assessment, right?

19 A. Right.

20 Q. And that's a very important

21 part of testing, is that the risk assessment

22 done as the threshold needs to be thorough,

23 right?

24 MR. GALLAGHER: Objection.

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1 Vague.

2 BY MR. SLATER:

3 Q. I'll ask it differently.

4 The risk assessment is the step

5 that's taken before you do the testing so

6 that you have thought through what you should

7 be looking for, correct?

8 A. The risk assessment is actually

9 in the very beginning of the development of

10 this particular valsartan process. So as a

11 QC, you know, you know, as a daily QC

12 operation, you don't do the risk, you know,

13 you know, you know, assessment, you know, at

14 that period.

15 Q. Well, if you get back --

16 rephrase.

17 If you have a customer like

18 Novartis that comes to you and says there's

19 unknown peaks, part of the way you then try

20 to study and figure out what those peaks are

21 is to do a risk assessment to figure out what

22 might they be so you know what you should

23 look for, correct?

24 A. Well, you know, you know, in

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1 this particular case with Novartis, you know,

2 they -- you know, in the very beginning, you

3 know, they were raising some specific, you

4 know, unknown impurities with a defined

5 retention time. Okay.

6 So throughout this process we

7 have been working with Novartis, you know, to

8 try to identify those little unknown peaks.

9 Q. When you were working with

10 Novartis to identify the peaks, did anybody

11 from ZHP tell Novartis that you knew that

12 NDMA is in the valsartan so that they would

13 know to look for the NDMA?

14 A. I don't think people involved,

15 you know, in the communications, you know,

16 directly with Novartis, you know, had that

17 knowledge before the events.

18 Q. Well, we know Peng Dong signed

19 off on this unknown peak report, and he was

20 on the e-mail in July of 2017, right?

21 A. He was. But I don't know how

22 much, you know, you know, you know, he really

23 went through, or -- basically, you know, I

24 didn't know what happened, you know, after

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1 Mr. Lin, you know, sent out his e-mail.

2 I mean, it looks like nobody

3 responded to anything, so I don't know.

4 People may just, as I said, for whatever the

5 reason, there's no, you know, resonance, I

6 will say.

7 Q. With regard to the risk

8 assessment that needed to be done -- well,

9 rephrase.

10 With regard to the risk

11 assessment, you pointed out it's done in the

12 very beginning when the process is developed.

13 But that's also an ongoing process, risk

14 assessment, during the lifecycle of the drug

15 substance, correct?

16 A. There is an ongoing, but

17 usually with a particular, you know, you

18 know, reason, yeah.

19 Q. So, for example, where a

20 customer says, there's unknown peaks, we want

21 to know what these are, we want to know what

22 these potential impurities are, that's a

23 reason to perform a risk assessment in

24 conjunction with the testing, right? That's

Page 234

1 good science, right?

2 A. Well, based upon, you know, you

3 know, you know, retrospective, you know, you

4 know, communications, right. And the ZHP

5 teams, you know, looks like, you know, focus

6 on what the customer, you know, communicated,

7 you know, to the team.

8 Q. Well, what I'm asking is this.

9 It's good science under these circumstances,

10 where a customer reports unknown peaks and is

11 concerned about impurities, to do a risk

12 assessment, evaluate the chemical reactions

13 that can occur, and have some idea of what

14 you're looking for, right?

15 That's good science, isn't it?

16 A. Well, usually what happen,

17 okay, when people, you know, you know -- you

18 know, first of all, okay, for a -- like a

19 residual solvent method, right, like a GC-FID

20 method, there is no -- like a threshold for

21 any unknown peak, you know, to be identified,

22 even as of today. Okay.

23 So when people talking about

24 these small unknown peaks, you know, that's

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1 how people, you know, treated it, you know,

2 initially as a technical issues, and so

3 people focus on trying to resolve, you know,

4 those identities, you know, to the customer.

5 Because the customer wanted to

6 have very specific answers, right, and so --

7 you know, so from my, you know,

8 understanding, you know, they -- at least at

9 the time they were not requesting, you know,

10 for anything other than they were, you know,

11 you know, requested.

12 So, yeah, so that's how, you

13 know, the focus of the ZHP team basically,

14 you know, just tried to, you know, meet, you

15 know, the needs of the customer to get the

16 answer to them as soon as -- you know, as

17 they can.

18 Q. The quickest way to get the

19 answer to Novartis would have been to tell

20 them that there was NDMA in the valsartan,

21 right?

22 A. As I said, the team, you know,

23 you know, the people involved, you know,

24 directly with the communication, you know,

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1 they -- you know, as I said, like you said,

2 you know, like Mr. -- although Mr. Peng Dong,

3 you know, he was signing off and he was on

4 the e-mail, but, you know, whatever, you

5 know, for that reason, you know, basically,

6 as I said, you know, Mr. Lin's e-mail just,

7 you know, for whatever reason didn't

8 generate, you know, any resonance.

9 Q. Well, it generated a report

10 that in April of 2018 you directed your team

11 not to complete and not to issue because

12 there was a sensitive impurity discussed.

13 A. This impurity --

14 MR. GALLAGHER: Objection.

15 BY MR. SLATER:

16 Q. Isn't that why it didn't

17 resonate?

18 MR. GALLAGHER: Objection.

19 Outside the scope, mischaracterizes

20 testimony, and mischaracterizes the

21 document.

22 A. As I indicated, you know, that

23 impurity is completely different from NDMA.

24 I mean, that's the N-nitroso derivative of

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1 irbesartan, so it's completely different.

2 BY MR. SLATER:

3 Q. Before we go back into this

4 report, I just want to make sure we're on the

5 same page.

6 The assessment of the potential

7 explanation for the impurities involves a

8 chemical analysis, right? You have to do

9 that analysis as part of the testing process,

10 right?

11 A. No. Well, typically you do a

12 mechanistic analysis, you know, based upon

13 that mechanistic analysis or based upon the

14 knowledge when this particular process was

15 developed, right.

16 And if the analysis, you know,

17 indicate there's some level of risk, then you

18 will follow up to do a -- what is called a

19 confirmatory testing.

20 But if the risk assessment, you

21 know, at that time, or if the knowledge, you

22 know, because of the knowledge gap, you know,

23 it didn't turn up as a risk, you -- you know,

24 you would not necessarily, you know, to do,



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1 you know, you know, an analysis.  
2 Q. Was CEMAT doing this testing  
3 that's represented in this unknown peak  
4 study?  
5 A. This particular work, you know,  
6 in this report, okay, it was done, you know,  
7 you know, you know, by the QC as well as, you  
8 know, with, you know, CEMAT, yes. So it's a  
9 combination, yes.  
10 Q. Were you involved?  
11 A. I was not directly involved.  
12 Q. Did you have visibility to it?  
13 Were you aware of what was being done?  
14 A. Well, only at the time, you  
15 know, they couldn't figure out, you know,  
16 some identities, you know, of a particular  
17 unknown peak, then they will come to me, you  
18 know, asking for possible solutions.  
19 Yeah, I did help him, you know,  
20 provided some strategies, you know, to help  
21 him -- to help them, you know, getting, you  
22 know, the elucidation of some, you know,  
23 unknown peaks.  
24 Q. And what strategies did you

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1 help with?  
2 A. One of the strategy that I told  
3 him to use is to use butyrate DMSO.  
4 The reason for that is, you  
5 know, quite a few of those interfering or  
6 background peaks, they were minor degradation  
7 products of DMSO, okay, with this particular  
8 method because DMSO, you know, you know,  
9 retrospectively that we found that, you know,  
10 it -- or during the process of this  
11 investigation we found out it will decompose  
12 to give, you know, a number of, you know,  
13 minor degradants.  
14 I think some of those are, you  
15 know, you know, mentioned in the reports,  
16 like dimethyl, you know, you know, sulfide or  
17 dimethyl disulfide.  
18 So the reason that I suggest  
19 them to use butyrate one is that, you know,  
20 you know, based upon the GC-MS analysis, you  
21 can -- if you see any peak, right, with what  
22 we call the mass shift, okay, and then we can  
23 basically, you know, understand, you know,  
24 the origin of that unknown peak, whether it's

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1 originated from DMSO or it's originated from  
2 some other reasons.  
3 MR. SLATER: Cheryll, let's go  
4 in this report to page 19 of 23,  
5 please. Or not.  
6 MS. CALDERON: You know what?  
7 MR. SLATER: Frozen?  
8 MS. CALDERON: I am frozen.  
9 Can you hear me?  
10 MR. SLATER: Yes.  
11 MS. CALDERON: Okay. Can you  
12 repeat what you said? Because I  
13 froze.  
14 MR. SLATER: Sure. If you  
15 could turn to page 19 of 23, please.  
16 MS. CALDERON: Okay. Sorry.  
17 MR. SLATER: No problem. The  
18 thing doesn't want to move.  
19 THE WITNESS: It's getting  
20 late.  
21 MR. SLATER: It's worn out.  
22 MS. CALDERON: Let me restart.  
23 MR. SLATER: I think you were  
24 there. Oh, okay.

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1 MS. CALDERON: How's that?  
2 MR. SLATER: I'll let you know  
3 when it comes up.  
4 Perfect. Scroll up a little  
5 tiny bit more, get the whole risk  
6 assessment in there. Perfect.  
7 BY MR. SLATER:  
8 Q. This study report of unknown  
9 peaks from May of 2018 contains a Risk  
10 Assessment here on page 19.  
11 Do you see that?  
12 A. Mm-hmm.  
13 Q. And the Risk Assessment says,  
14 "It is shown from above, each unknown peak  
15 has either been identified or the source of  
16 which identified, and the results are far  
17 lower than the specification by quantitative  
18 analysis." I want to stop there.  
19 The reference to  
20 "specification" has to do with already  
21 identified solvents or other substances that  
22 you already know may be there, correct?  
23 A. In this particular case, yes.  
24 It looks like utilizing 10 percent of the



<p style="text-align: right;">Page 242</p> <p>1 toluene ICH, you know, standard.</p> <p>2 Q. And it says, "Control of these</p> <p>3 unknown peaks by comparing to the peak area</p> <p>4 of 10 percent toluene (ICH limit 89 parts per</p> <p>5 million) presents no risk." And then it</p> <p>6 says, "Please refer to the following table</p> <p>7 for details."</p> <p>8 I want to stop there. When it</p> <p>9 refers to 89 parts per million presenting no</p> <p>10 risk, is that a judgment that was made that</p> <p>11 as long as something that's not identified is</p> <p>12 less than 89 parts per million, you don't</p> <p>13 have to worry about it?</p> <p>14 A. Well, this 89 percent numbers</p> <p>15 or criteria, based upon, you know, what I was</p> <p>16 told, you know, it came from one of Novartis'</p> <p>17 document.</p> <p>18 So basically during -- in our</p> <p>19 conversation, you know, at least at one time,</p> <p>20 the Novartis practice was that, you know, at</p> <p>21 that time, you know, you do not necessarily</p> <p>22 need to investigate any unknown peaks, okay,</p> <p>23 with peak area lower than toluene, you know,</p> <p>24 standard of -- you know, or toluene, you</p>	<p style="text-align: right;">Page 244</p> <p>1 the conclusion on page 23 of 23. Can</p> <p>2 you scroll up just a little bit just</p> <p>3 so we capture the bottom of the</p> <p>4 conclusion, please? Perfect.</p> <p>5 Q. The conclusion of the report</p> <p>6 repeats the risk assessment, saying that "The</p> <p>7 unknown peaks can be controlled by comparing</p> <p>8 to the peak area of 10 percent toluene, ICH</p> <p>9 limit (89 parts per million). The product</p> <p>10 quality is less likely to be impacted."</p> <p>11 Same conclusion as the risk</p> <p>12 assessment, right?</p> <p>13 A. Mm-hmm, yes.</p> <p>14 Q. Now, in retrospect, there was</p> <p>15 NDMA there, and that was affecting the</p> <p>16 quality of the product, right?</p> <p>17 A. Yes. But here, you know, the</p> <p>18 subject of this investigation, you know,</p> <p>19 would focus on that nine, you know, unknown</p> <p>20 peaks. So that conclusion was made based</p> <p>21 upon assessment of those nine unknown peaks.</p> <p>22 So NDMA was not among one of them.</p> <p>23 Q. Okay. Well, when you say NDMA</p> <p>24 was not among them, NDMA was not being looked</p>
<p style="text-align: right;">Page 243</p> <p>1 know, reference solution has 89, you know,</p> <p>2 ppm concentrations.</p> <p>3 Q. Coming back to my question, it</p> <p>4 appears to me the risk assessment was as long</p> <p>5 as an unknown peak is less than 89 parts per</p> <p>6 million, there's no risk; you don't have to</p> <p>7 be concerned about it even if you can't</p> <p>8 identify what it is.</p> <p>9 Do I understand that correctly?</p> <p>10 A. No. That's not what it says.</p> <p>11 I mean, basically, you know, it looks like</p> <p>12 whoever made that risk assessment, you know,</p> <p>13 people utilized, you know, what Novartis at</p> <p>14 least, you know, you know, had done, you</p> <p>15 know, at one point.</p> <p>16 Because even as of today, you</p> <p>17 know, as to what a threshold, you know, you</p> <p>18 need to identify for unknown peaks with</p> <p>19 GC-FID method. Is still -- there's no fixed</p> <p>20 answer to that.</p> <p>21 Q. Well, the answer is that the</p> <p>22 NDMA -- well, rephrase. We'll come back to</p> <p>23 it.</p> <p>24 MR. SLATER: Let's go now to</p>	<p style="text-align: right;">Page 245</p> <p>1 for because nobody actually said we need to</p> <p>2 look for NDMA, right?</p> <p>3 A. Well, whoever -- you know, you</p> <p>4 know, people doing this particular, you know,</p> <p>5 or people -- I mean, particularly the main --</p> <p>6 you know, the main author, right, you know,</p> <p>7 of this investigation, he had no knowledge.</p> <p>8 Q. And he didn't -- he didn't do</p> <p>9 or didn't have available to him a risk</p> <p>10 assessment advising of the potential</p> <p>11 development of NDMA, right? That was not</p> <p>12 provided, correct?</p> <p>13 A. I don't know whether, you know,</p> <p>14 somebody provide it or not. But based upon,</p> <p>15 you know, what's presented here, you know, it</p> <p>16 looks like the risk assessment was solely</p> <p>17 based upon, you know, that nine unknown</p> <p>18 peaks.</p> <p>19 Q. And the person who authored</p> <p>20 this report certainly didn't document knowing</p> <p>21 what was known by others in the company, that</p> <p>22 there was NDMA in the drug substance,</p> <p>23 correct?</p> <p>24 A. As I said, you know, the main</p>

<p>Page 246</p> <p>1 author, he had no knowledge.</p> <p>2 MR. SLATER: Why don't we go</p> <p>3 off the record for a second.</p> <p>4 THE VIDEOGRAPHER: The time</p> <p>5 right now is 12:13 p.m. We're now off</p> <p>6 the record.</p> <p>7 (Whereupon, a recess was</p> <p>8 taken.)</p> <p>9 THE VIDEOGRAPHER: The time</p> <p>10 right now is 12:26 p.m. We're back on</p> <p>11 the record.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. So we have on screen</p> <p>14 Exhibit 213, which is an FDA Warning Letter</p> <p>15 dated November 29, 2018.</p> <p>16 Do you see that?</p> <p>17 A. Mm-hmm.</p> <p>18 Q. And you understand this warning</p> <p>19 letter followed from the FDA inspection from</p> <p>20 July 23 to August 3 at ZHP's facilities,</p> <p>21 correct?</p> <p>22 MR. GALLAGHER: Objection.</p> <p>23 Outside the scope.</p> <p>24 You can answer to the extent</p> <p>Page 247</p>	<p>Page 248</p> <p>1 Q. The FDA advised your company,</p> <p>2 "Our investigators also noted other examples</p> <p>3 of your firm's inadequate investigation of</p> <p>4 unknown peaks observed in chromatograms."</p> <p>5 I want to stop there. That's</p> <p>6 what we were just talking about, is ZHP's</p> <p>7 study report on unknown peaks in May of 2018,</p> <p>8 correct?</p> <p>9 A. I'm sorry, say that again?</p> <p>10 Q. We were just discussing the</p> <p>11 study report of unknown peaks in residual</p> <p>12 solvent of valsartan a few moments ago,</p> <p>13 correct?</p> <p>14 A. Right, mm-hmm.</p> <p>15 Q. And here the FDA's pointing out</p> <p>16 that they thought that the investigation of</p> <p>17 unknown peaks observed in chromatograms was</p> <p>18 inadequate.</p> <p>19 That's what the FDA found,</p> <p>20 correct?</p> <p>21 A. That's what they statement. I</p> <p>22 think we had a -- you know, an explanation</p> <p>23 and a response.</p> <p>24 Q. This points out, "For example,</p> <p>Page 249</p>
<p>1 you know personally.</p> <p>2 A. Well, that I know, it's issued</p> <p>3 after the inspection.</p> <p>4 Q. Right. And you can see in the</p> <p>5 first paragraph the dates of the inspection</p> <p>6 were July 23 to August 3, 2018.</p> <p>7 Do you see that?</p> <p>8 A. Yeah, mm-hmm.</p> <p>9 Q. So if we scroll down a little</p> <p>10 further down on this page, deviation number 1</p> <p>11 is titled, "Failure of your quality unit to</p> <p>12 ensure that quality-related complaints are</p> <p>13 investigated and resolved." Right?</p> <p>14 A. I saw the title.</p> <p>15 MR. SLATER: Let's go down to</p> <p>16 the next page and look at part of what</p> <p>17 was discussed somewhat relevant to</p> <p>18 what we just talked about.</p> <p>19 You can scroll down further,</p> <p>20 Cheryll, because I want to -- that's</p> <p>21 good right there. Thank you.</p> <p>22 Q. So you see a paragraph that</p> <p>23 starts with the word "Our investigators"?</p> <p>24 A. Mm-hmm.</p>	<p>1 valsartan intermediates," and it gives some</p> <p>2 numbers of those batches, "failed testing for</p> <p>3 an unknown impurity (specification less than</p> <p>4 or equal to 0.5 percent) with results of</p> <p>5 0.56 percent for both batches. Your action</p> <p>6 plan indicated that the impurity would be</p> <p>7 identified as part of the investigation;</p> <p>8 however, you failed to do this."</p> <p>9 A. No, we did that, actually. We</p> <p>10 did afterward. I mean, at the time of this</p> <p>11 warning letter, you know, the investigation,</p> <p>12 I think, was still ongoing, okay.</p> <p>13 So actually as part of the --</p> <p>14 you know, of the CAPA or the commitment, you</p> <p>15 know, we actually, you know, did an</p> <p>16 investigation, but we didn't resolve, you</p> <p>17 know, the whole structure, okay.</p> <p>18 And we, you know, you know, we</p> <p>19 told the, you know, the investigator, you</p> <p>20 know, this is a process impurity, you know,</p> <p>21 structurally related to that of valsartan</p> <p>22 intermediate. But we didn't know its exact</p> <p>23 structure, right?</p> <p>24 So, yeah, so the investigation</p>

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1 was ongoing, and eventually, you know, we  
2 resolved, you know, you know, that structure,  
3 okay.  
4 Q. You said you resolved that  
5 structure.  
6 A. Right.  
7 Q. You mean you find NDMA?  
8 A. Yes, finally with NMR we were  
9 able to identify those structures, yes, and  
10 which is confirmed it is a process-related,  
11 you know, impurity of that intermediate.  
12 Q. But by this time it was already  
13 identified as NDMA, right?  
14 A. You mean by the time of --  
15 yeah, of this warning letter, yeah. NDMA,  
16 yes, that already was identified. But this  
17 is -- you know, FDA was talking about, you  
18 know, this is, you know, a completely  
19 different impurity. Yeah.  
20 Q. What do you mean, the FDA's  
21 saying it's a completely different impurity?  
22 A. Well, you know, here they  
23 specifically pointing out to -- you know, to  
24 that, you know, particular impurity, you

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1 know, given a value of 0.56 percent, right?  
2 Yeah. So, yeah, so that's not an NDMA or any  
3 other nitroso, you know, compound.  
4 Q. So coming back to the FDA's  
5 comments, they're indicating that --  
6 rephrase.  
7 Coming back to the FDA's  
8 warning letter, the FDA stated your action  
9 plan, that would be ZHP's action plan, given  
10 on a prior date, correct?  
11 A. Yeah, our plan is, you know, we  
12 will continue, you know, to do, you know, the  
13 structure elucidation, okay.  
14 Basically, you know, as part  
15 of, like, this OOS investigation, okay,  
16 although, you know, we tried to identify  
17 unknown peaks as soon, you know, or as  
18 quickly as possible, but sometimes, you know,  
19 an unknown peak, you know, structure takes  
20 time, right.  
21 So during that kind of, you  
22 know, you know, situation, what you can do  
23 is, you know, basically once we know, you  
24 know, you know, the basic information of this

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1 particular impurity, and also I think we did  
2 the assessment at the time, this impurity is  
3 just not -- you know, actually was not being  
4 carried over into the downstream product,  
5 right?  
6 So, therefore, you know, the  
7 risk was, you know, was very limited or  
8 negligible. So that's how, you know, QA  
9 decided, you know, to, you know, basically to  
10 close the main investigation, but with a  
11 follow-up, you know, cover. Okay. That's a  
12 very typical, you know, way, you know, you  
13 know, in the industry, you know, to do those,  
14 like, impurity related, you know,  
15 investigation.  
16 Q. Well, the FDA didn't seem happy  
17 with status of the investigation.  
18 A. Well, that's -- I think that's  
19 their, you know, misunderstanding, you know,  
20 from my perspective.  
21 So I think, as I said, during  
22 the final meetings or the last meeting, you  
23 know, being on-site at FDA, and also in our  
24 follow-up, you know, responses, you know, we

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1 stated very clearly, you know, you know, to  
2 the FDA, you know, this follow-up action has  
3 been completed. Yeah.  
4 Q. The FDA continues to state,  
5 "Additionally, residual solvent chromatograms  
6 for valsartan API validation batches  
7 manufactured using your zinc chloride  
8 process, with DMF in 2012," and then it gives  
9 the three validation batch numbers, "show at  
10 least one unidentified peak eluting after the  
11 toluene peak in the area where the presence  
12 of NDMA was suspected to elute."  
13 A. Again, you know, this peak, as  
14 I indicated to you, based upon our  
15 retrospective analysis, that first, you know,  
16 you know, visible, you know, small peaks  
17 based upon our investigation, it was n-butyl  
18 acetate.  
19 Q. And I think you explained the  
20 NDMA was right next to that.  
21 A. It's on the shoulder. As I  
22 said, after if we inject it with a, you know,  
23 a more concentrated sample, like a pure  
24 sample, right, and -- you know, then we would

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1 find out.  
2 But in the chromatogram of a  
3 real sample, right, you know, like we analyze  
4 using the GC-FID method.  
5 To analyze a real sample, the  
6 NDMA peak was basically, you know, submerged  
7 with, overwhelmed by this, you know,  
8 proceeding peak which is the n-butyl acetate.  
9 Q. As a matter of good  
10 manufacturing practices, it's not acceptable  
11 to do a test, not identify the peak, and just  
12 say, well, it's pretty small, so we don't  
13 really have to worry about identifying it.  
14 That's not acceptable, right?  
15 MR. GALLAGHER: Objection.  
16 Vague, and calls for speculation.  
17 A. We follow ICH guidance, okay,  
18 in terms of, you know, what needs to be  
19 identified, what -- you know, you know, you  
20 do not necessarily need to identify it.  
21 BY MR. SLATER:  
22 Q. It's not acceptable where  
23 you're trying to identify what an unknown  
24 peak is to run your standard test, not

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1 identify it, and just assume it's fine,  
2 because you know that even something with a  
3 very, very small peak, something that's  
4 barely perceptible, if it's a  
5 mutagenic/genotoxic impurity, that can be  
6 dangerous and can't be in the product, right?  
7 MR. GALLAGHER: Objection.  
8 Vague, lacks foundation, and compound.  
9 A. You know, for those very  
10 low-level potential genotoxic impurity, you  
11 would need to develop a specific method,  
12 okay, to -- you know, to detect them, to  
13 control them, okay.  
14 For any other method, right,  
15 like, for example, this residual solvent  
16 method, they just are not adequate, okay, to  
17 look for those unknown peaks, okay.  
18 Time again, you know, I mean,  
19 you know, based upon our retrospective  
20 investigation, you know, the GC-FID method is  
21 just -- you know, its intended -- its  
22 original intended purpose is to monitor those  
23 residual solvents. That's its intended  
24 purpose.

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1 So its intended purpose is not  
2 to, you know, identify, you know, any little,  
3 you know, you know, unknown peaks, right?  
4 So, you know, and once again,  
5 as I mentioned, even as of today, in ICH Q3C,  
6 which is the most relevant ICH guidance  
7 governing the residual solvent, okay, even in  
8 that guidance today there is no specific  
9 requirement in terms of, you know, above what  
10 threshold an unknown peak need to be  
11 identified.  
12 Q. One of the things that you need  
13 to know as a drug manufacturer is the  
14 limitations of GC-FID.  
15 That's one thing you need to be  
16 aware of, right?  
17 A. Well, it's all depends upon  
18 what's the intended purpose, right? So with  
19 the intended purpose for the residual  
20 solvents, the GC-FID method is perfectly  
21 suitable for that purpose.  
22 Q. Well -- rephrase.  
23 Here you had unknown peaks,  
24 didn't know what they were, according to the

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1 documents, and made a decision, it's a low  
2 amount, we don't have to be concerned.  
3 That was the decision that was  
4 made, right?  
5 A. Look, as I -- once again, you  
6 know, with the GC-FID method, okay, if you go  
7 into any pharmaceutical company, okay,  
8 including like my former, you know, employer,  
9 right, Merck & Company or any other, you  
10 know, like Schering-Plough, you know, these  
11 are the very famous, you know, multinational  
12 companies, okay, you know, people will not --  
13 you know, for a residual solvent method, they  
14 will not going through every tiny little  
15 peaks to identify, you know, what they are,  
16 okay, you know, at least, you know, you know,  
17 before, you know, that event came out, right?  
18 So -- so basically, you know,  
19 as I said, you know, it's -- you know, you  
20 will need to know, okay, and also it need to  
21 be above -- you know, like, for example, like  
22 in our conversation with Novartis or with  
23 some other, you know, you know, customers,  
24 right, they were, you know, also, at least



<p style="text-align: right;">Page 258</p> <p>1 some of them, they were not sure, you know,                  2 what a specific threshold, you know, it need                  3 to be set.                  4 So, but from our perspective,                  5 if customer had that particular request for                  6 certain specific, you know, unknown peaks,                  7 yeah, we will do the investigation and try                  8 to, you know, identify or try to find, you                  9 know, the potential source, you know, you                  10 know, for those unknown peaks.                  11 Q. It sounds like you're telling                  12 me it's really hard to find it, but Novartis,                  13 plus using an outside lab, they found the                  14 NDMA, and it wasn't even their drug                  15 substance. They found it before ZHP did on                  16 these chromatograms, is what you're -- and                  17 you're telling me it was too hard to figure                  18 it out?                  19 A. Yes. Don't forget, these are                  20 the two different methods, okay? Two                  21 different methods, you know, you know, their                  22 critical, you know, method parameters, they                  23 are quite different. Okay.                  24 Even for GC-FID, if you run on</p>	<p style="text-align: right;">Page 260</p> <p>1 question, Novartis, enlisting the help of an                  2 outside lab, identified the NDMA, right? It                  3 wasn't so hard to do. They did it, right?                  4 A. Look, we supplied Novartis,                  5 right, you know, all material like commercial                  6 skill batches, at least, you know, by the end                  7 of 2017, right. And they received, you know,                  8 a lot of those.                  9 So from there, you know, I                  10 mean, I don't know why they, you know, you                  11 know, sended it to the outside lab or                  12 whatever.                  13 So at least, you know, they --                  14 usually, when you go into business trying to                  15 have a new, you know, vendor, you know, you                  16 will do the analysis or in-depth, you know,                  17 you know, analysis, you know, for the sample                  18 that you're going to be for your commercial,                  19 you know, productions.                  20 So during that period, you                  21 know, Novartis, you know, their own lab, you                  22 know, still not was able to find. So my                  23 guess is, you know, once they contract this                  24 out to a certain lab, they just happen to be,</p>
<p style="text-align: right;">Page 259</p> <p>1 different instrument, sometimes, you know,                  2 the sensitivity can be vary quite a bit.                  3 Okay.                  4 So, you know, and also, you                  5 know, some of our customer, they had a, you                  6 know, similar question regarding the unknown                  7 peaks, right? They also did a GC-MS                  8 analysis. Okay, they didn't, you know, find,                  9 you know, you know, NDMA.                  10 I mean, and also we supply, you                  11 know, our product, right, with the zinc                  12 chloride. You know, I think shortly after                  13 the zinc chloride, you know, was approved by,                  14 you know, regulators, right, we supplied to                  15 Novartis', you know, subsidiary company,                  16 Sandoz, right. Sandoz, at least at that                  17 time, was part of Novartis.                  18 So we supply Sandoz valsartan                  19 for quite, you know, long period. And so as                  20 a unit of Novartis, you know, they haven't                  21 had any, you know, you know, issues, or                  22 didn't, you know, even have questions, I                  23 think, as far as I understand, okay.                  24 Q. Just to get back to my</p>	<p style="text-align: right;">Page 261</p> <p>1 you know, utilizing a different, you know,                  2 you know, method.                  3 Okay. That method, it appears                  4 to be, you know, somewhat more sensitive than                  5 ZHP's method. Okay.                  6 So if we -- you know, if                  7 someone would keep using that -- you know,                  8 you know, that condition that's originally                  9 intended for the GC-FID, you know, I think                  10 it's very fair to say, you know, NDMA, you                  11 know, at the -- you know, the level that's                  12 produced or that's present, you know, you                  13 know, you know, in ZHP's batches, you know,                  14 it was very difficult, if not entirely                  15 possible, I mean, to be adequately detected.                  16 Okay.                  17 Q. You're aware that starting in                  18 2014, complaints came in on a pretty regular                  19 basis from your customers pointing out                  20 unknown peaks and asking for answers.                  21 You do know that there were                  22 multiple complaints and requests for                  23 information, right?                  24 MR. GALLAGHER: Objection.</p>



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1 Vague, and lacks foundation.  
 2 You can answer.  
 3 A. Yeah. I mean -- yeah, I mean,  
 4 retrospectively, you know, you know, for  
 5 some -- you know, you know, during the later  
 6 stage of the investigation, you know, you  
 7 know, yeah.  
 8 For example, with Novartis,  
 9 also with Sun Pharma at the time, yeah, I  
 10 was -- you know, later was also being  
 11 consulted, you know, you know, how to, you  
 12 know, address the origin or the identity.  
 13 But essentially, you know, it's  
 14 the same set of the, you know, phenomenon,  
 15 right? And so my guess is, you know, in our  
 16 registered DMF or whatever, you know, the  
 17 other kind of dossier, you know, you know, we  
 18 just supplied to those customers, right,  
 19 within -- you know, using the same set of  
 20 documents, right?  
 21 And in those, you know,  
 22 regulatory approved documents, you know,  
 23 there was no, you know, specific information  
 24 about, you know, some of those peaks. So

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1 that's why, you know, you know, some people,  
 2 you know, they turn out to be having, you  
 3 know, the same kind of question.  
 4 But again, you know, you know,  
 5 based upon my, you know, knowledge, you know,  
 6 first of all, you know, they -- initially at  
 7 least, they all concentrated on relatively  
 8 large peaks. And they ask for a certain  
 9 specific, you know, set of peaks, right, and  
 10 then we work with them, you know.  
 11 And also for some of the later  
 12 coming in, you know, questions, we would  
 13 sometimes utilize, you know, the previously,  
 14 you know, obtained results to help answer.  
 15 For example, like in Novartis'  
 16 cases, like I think we utilized some of the  
 17 results, you know, we provided to Sun Pharma.  
 18 And again, you know, some of  
 19 those company, they have been, you know,  
 20 continuously, you know, you know, you know,  
 21 buying, you know, commercial batches of --  
 22 you know, of, you know, valsartan, up to a  
 23 point that, you know, we sent out the notice,  
 24 you know, for suspension and also for recall.

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1 BY MR. SLATER:  
 2 Q. Coming back to my question,  
 3 you're aware that there were multiple  
 4 complaints made by customers in 2014, 2015,  
 5 2016, 2017, and 2018, saying that there were  
 6 unknown peaks on their own testing, and they  
 7 were looking for answers from ZHP as to what  
 8 was the cause of those peaks.  
 9 That's a correct statement,  
 10 right?  
 11 MR. GALLAGHER: Objection.  
 12 Lacks foundation.  
 13 THE WITNESS: Sorry.  
 14 MR. GALLAGHER: Go ahead.  
 15 A. As I indicated, I didn't know,  
 16 or I was not informed, you know, initially.  
 17 And in some of those conversation, you know,  
 18 late in the investigation, as I said, I was  
 19 being consulted, you know, you know, or I was  
 20 try -- you know, they tried to pull me to  
 21 help them to find out, you know, you know,  
 22 the identity or the potential sources.  
 23 BY MR. SLATER:  
 24 Q. All I'm asking is to confirm --

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1 rephrase.  
 2 All I'm looking to confirm  
 3 right now is -- rephrase.  
 4 You can confirm for me that  
 5 starting in 2014 with Ranbaxy and Sun Pharma,  
 6 then Vertex, then Glenmark, then Sun Pharma,  
 7 then Aurobindo, then Novartis, from 2014 to  
 8 2018, there were repeated customer complaints  
 9 pointing to unknown peaks, correct?  
 10 MR. GALLAGHER: Objection.  
 11 Vague, lacks foundation, asked and  
 12 answered.  
 13 A. Some of those, they were  
 14 treated as technical, you know, exchange,  
 15 okay? And some of the customer, you know,  
 16 you know, you know, at the time they, you  
 17 know, they have this question, they were  
 18 already, you know, receiving our commercial,  
 19 you know, batches, as far as I know.  
 20 So they just wanted to know a  
 21 little bit further, you know, the identity  
 22 of, as I said, a certain specific numbers of  
 23 unknown peaks. Okay.  
 24 Every time -- I mean, you know,

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1 basically they are the same set of the  
 2 unknown peaks, right?  
 3 And as I said, you know, the  
 4 reason why different company ask, you know,  
 5 those questions is, my guess is probably  
 6 because, you know, in our, you know, official  
 7 documents, right, like the DMF or some other,  
 8 you know, regulatory approved documents, you  
 9 know, in there, there was, you know, no  
 10 information on some of those, like, very  
 11 small peaks. So -- you know, so, yes.  
 12 So it's the same kind of  
 13 questions, and every time, as I said, we  
 14 tried to do, you know, what we can to  
 15 identify these peaks.  
 16 I think, you know, in the end,  
 17 you know, we -- for all of the concerned  
 18 peaks, you know, I think, you know, we were  
 19 able to find the identity or the potential  
 20 sources.  
 21 Q. You realize these companies  
 22 that were complaining to ZHP about these  
 23 unknown peaks, they weren't asking for the  
 24 information because they were curious. They

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1 were asking what those peaks represented  
 2 because they had quality obligations and GMP  
 3 obligations and wanted to make sure that the  
 4 substance they were purchasing from ZHP met  
 5 the quality standards and was safe.  
 6 That's why they were asking,  
 7 right?  
 8 MR. GALLAGHER: Objection.  
 9 Lacks foundation, and calls for  
 10 speculation.  
 11 A. It's a continuous process for  
 12 improvement. And, you know, that's why, you  
 13 know, you know, we understand our customers'  
 14 concerns, right?  
 15 That's why every time, you  
 16 know, they have a question, we responded, you  
 17 know, and we trying to resolve, you know, the  
 18 issue as well as, you know, possible.  
 19 And particularly during my, you  
 20 know, you know, review of some of the  
 21 documents, you know, with Novartis, you know,  
 22 I think like in late May 2018, you know,  
 23 there's one e-mail from Novartis, you know,  
 24 they -- you know, they thank us, you know, to

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1 get the results, you know, they need like  
 2 very -- you know, very quickly.  
 3 But, you know, again, as I  
 4 said, those regulatory document, you know, we  
 5 have the agency or regulatory, you know,  
 6 approve the specification at the time.  
 7 BY MR. SLATER:  
 8 Q. The responsibility for the  
 9 quality of the valsartan API was ZHP's  
 10 responsibility, right?  
 11 A. Yes.  
 12 Q. And despite -- rephrase.  
 13 Despite that, Novartis  
 14 identified the NDMA before ZHP did in  
 15 June 2018, right?  
 16 A. It's the third-party lab, okay,  
 17 and they -- you know, initially, you know,  
 18 they tentatively identified, and they  
 19 communicated it to us.  
 20 And upon the receipt of the  
 21 information, we immediately, you know,  
 22 purchased the reference materials, developed  
 23 method, and -- yeah, so we very quickly  
 24 confirmed their results.

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1 And also, within a very short  
 2 period of time, we developed an adequate  
 3 quantitative methods. So we will be able  
 4 to very quickly to come up with, you know,  
 5 you know, quite reliable NDMA results, okay,  
 6 in those, you know, batches, particularly  
 7 those batches, you know, you know, we  
 8 discussed with Novartis.  
 9 Q. Well, just to be clear, ZHP  
 10 already knew that the NDMA was in the  
 11 valsartan, we've already established that, at  
 12 least as of July 2017.  
 13 A. As I told you, at that time,  
 14 you know, Mr., you know, Lin's, you know,  
 15 e-mail, you know, as I said, it looks like  
 16 didn't go far.  
 17 So company as a whole, you  
 18 know, it didn't have that knowledge until,  
 19 you know, receiving that Novartis, you know  
 20 e-mails.  
 21 Q. Well, what happened was  
 22 Novartis figured out that there was NDMA  
 23 there, enlisting the services of a  
 24 third-party lab to help it, and then

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1 basically told ZHP that ZHP needed to take  
 2 the steps to notify the authorities and take  
 3 steps to deal with the severe quality  
 4 problem.  
 5 That's the only reason ZHP told  
 6 anybody what happened here, was because  
 7 Novartis pushed you to do it, right?  
 8 A. No.  
 9 MR. GALLAGHER: Objection.  
 10 Vague, lacks foundation.  
 11 BY MR. SLATER:  
 12 Q. If Novartis had not come along,  
 13 there's no reason to believe that ZHP would  
 14 have told anybody about the NDMA, right?  
 15 MR. GALLAGHER: Objection.  
 16 A. That's your speculation.  
 17 MR. GALLAGHER: Lacks  
 18 foundation.  
 19 BY MR. SLATER:  
 20 Q. We know that in July of 2017,  
 21 it was discussed in an e-mail that valsartan  
 22 had NDMA in it, and ZHP didn't tell anybody  
 23 about that, right?  
 24 A. My answer -- you know, I think

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1 I already answered that question multiple  
 2 times.  
 3 Q. Well, let's look right in the  
 4 middle of the page where we just went through  
 5 this -- well, rephrase.  
 6 Looking now at the middle of  
 7 this page in Exhibit 213, the FDA Warning  
 8 Letter of November 2018, it says, "Your  
 9 response states that NDMA was difficult to  
 10 detect. However, if you had investigated  
 11 further, you may have found indicators in  
 12 your residual solvent chromatograms alerting  
 13 you to the presence of NDMA."  
 14 And then they point out, the  
 15 FDA says, "For example, you told our  
 16 investigators you were aware of a peak that  
 17 eluted after the toluene peak in valsartan  
 18 API residual solvent chromatograms where the  
 19 presence of NDMA was suspected to elute."  
 20 So -- and then they say -- just  
 21 to be clear, they say, "At the time of  
 22 testing, you considered this unidentified  
 23 peak to be noise and investigated no  
 24 further." So I want to stop there.

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1 You certainly would agree with  
 2 me that the FDA's right; that you stopped  
 3 your investigation before figuring out the  
 4 answer, and then it was only when Novartis  
 5 figured it out that the answer came out,  
 6 right?  
 7 MR. GALLAGHER: Objection.  
 8 Mischaracterizes testimony, and lacks  
 9 foundation.  
 10 You can answer.  
 11 A. Let me give you a -- I try to  
 12 give you a full answer, okay, part by part or  
 13 little by little. Okay?  
 14 The FDA statement, the first  
 15 one says, "Your response states that NDMA was  
 16 difficult to detect," okay?  
 17 So this was -- FDA's basically  
 18 repeating our language at the time, right?  
 19 Okay. If you look at, you know, Dr. Janet  
 20 Woodcock's statement, okay, she released  
 21 during January -- in January 2019, right  
 22 after, you know, this event came out, in  
 23 that, you know, statement, you know, there is  
 24 one sentence, something like, you know, it

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1 said, the -- like, the property of NDMA made  
 2 it difficult to be detected by, like, a  
 3 normal or routine analytical test method.  
 4 Something like that. Okay.  
 5 So, you know, so basically  
 6 combining everything that I told you, you  
 7 know, with the GC-FID method, okay, you know,  
 8 again, you know, you know, this peak, right,  
 9 that I -- you know, that we told, you know,  
 10 this particular inspector, right, the peak  
 11 eluting after the toluene, you know, as I  
 12 said, this is not NDMA.  
 13 NDMA is just -- yeah, just at  
 14 the noise level, you know. As I said, at the  
 15 NDMA in the real sample, you know, it was  
 16 just among the smallest, you know, peaks,  
 17 okay. So it's -- you know, it's just that --  
 18 you know, at that kind of level.  
 19 So that's -- you know, that's  
 20 exactly what happened. I mean, all right.  
 21 So you know, basically, again, as I  
 22 indicated, you know, the nature of the GC-FID  
 23 method is not designed to detect, you know,  
 24 such low level peaks. Its purpose is to

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1 monitor, you know, the residual solvents  
2 that, you know, that one particular process  
3 utilized, you know, in that process.  
4 So from that perspective, you  
5 know, that GC-FID residual solvent method is  
6 still, you know, suitable. Okay. I think  
7 that, you know, we're still utilizing this  
8 residual solvent method, okay, to release the  
9 valsartan API or drug substances, okay, to,  
10 you know, European, you know, customers,  
11 after we modify, you know, the process of  
12 valsartan API.  
13 BY MR. SLATER:  
14 Q. ZHP modified its SOPs so that  
15 following this revelation to the public about  
16 the NDMA, now you're required to use GC-MS to  
17 identify unknown peaks as a matter of course,  
18 right?  
19 MR. GALLAGHER: Objection to  
20 form.  
21 A. Well --  
22 BY MR. SLATER:  
23 Q. That's what the SOP says now,  
24 right?

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1 A. Our SOP -- yeah, because of --  
2 yeah, based upon -- yeah, based upon the  
3 investigation, or the outcome, you know, of  
4 the investigation, our SOP now requires any  
5 unknown peaks, okay, with a signal-to-noise  
6 greater than 10 would be investigated, okay?  
7 And both FDA and also regulatory agency, they  
8 agree with this threshold, okay? So that's  
9 number one, all right?  
10 And since then we have done  
11 tremendous, you know, you know, amount of  
12 testing utilizing GC-MS, even GC-MS/MS,  
13 right, and we have done so many tests. And  
14 so far we were not able to find another  
15 nitrosamine, you know, you know, you know,  
16 with this approach. Okay?  
17 Q. Well, if you're talking about  
18 batching going forward, you were required to  
19 optimize the process so you wouldn't form  
20 nitrosamines, right?  
21 A. Nitrosamine could still be  
22 present, okay, based upon the nature of the  
23 chemistry. Okay? It all depends upon how  
24 much, right?

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1 Right now, you know, I can tell  
2 you it's way below the detection limit of the  
3 original detection limit that we established,  
4 you know, after these events, because, as I  
5 mentioned to you in the very beginning, FDA,  
6 you know, the original position was it should  
7 be absent, right?  
8 So based upon FDA's, you know,  
9 published analytical method for NDMA as well  
10 as for NDEA, and for NDMA the FDA's, you  
11 know, limit of quantitation is 5 ppb, okay.  
12 For NDEA the limit was 1 ppb, right? So our  
13 valsartan now is able to meet both, you know,  
14 you know, you know, requirement.  
15 Although, as I said, you know,  
16 you know, FDA has basically retreated, you  
17 know, from their original position, right?  
18 Now it's being allowed, you know, you know,  
19 you know, for example, like for NDMA, now  
20 they allow, you know, 96 nanogram per day,  
21 which would translate into 300 ppb's, okay?  
22 And so our product, our, you  
23 know, valsartan utilized this newly, you  
24 know, developed or modified process. Okay.

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1 We are able to generate, you know, you know,  
2 valsartan way below, you know, the 300 ppb,  
3 okay? So it's below, you know, you know, 5  
4 ppb. So it's 60 times lower, you know, for  
5 the method, the detection limit.  
6 MR. SLATER: Let's look at  
7 page 4 of the warning letter, Cheryl,  
8 if you're still there. Thank you.  
9 Okay. Could you scroll up a little  
10 bit more, please?  
11 Q. Okay. Under number 2, the  
12 second paragraph, starting with the second  
13 sentence, the FDA advised you, "You are  
14 responsible for developing and using suitable  
15 methods to detect impurities when developing,  
16 and making changes to your manufacturing  
17 processes. If new or higher levels of  
18 impurities are detected, you should fully  
19 evaluate the impurities and take action to  
20 ensure the drug is safe for patients."  
21 My first question is, do you  
22 see what I just read?  
23 A. Let's see. Which paragraph?  
24 I'm sorry.

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1 Q. Second paragraph under  
2 number 2.  
3 A. Second paragraph. Oh, starting  
4 with "You also failed to," right?  
5 Q. Yes.  
6 A. Okay. Let me read through.  
7 I'm sorry. It's getting a little bit too  
8 long. You also... okay.  
9 (Witness reviewing document.)  
10 A. So I don't know, you know,  
11 whether this is specifically referenced here.  
12 If here, you know, FDA specifically, you  
13 know, referring to NDMA issue, I think this  
14 is in a statement, you know, after the fact.  
15 Q. This is my question. You saw  
16 what I just read, right?  
17 A. Yeah. I read through the  
18 second paragraph, yes.  
19 Q. You would agree with me that  
20 that is a correct statement of ZHP's  
21 responsibilities under good manufacturing  
22 practices, right?  
23 A. See, the precondition here is  
24 you need to know, or you have that knowledge,

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1 at the time of the process change. So that  
2 process change was made somewhere around 2011  
3 to 2012.  
4 Q. The point is, you would agree  
5 that ZHP, like any drug manufacturer, is  
6 responsible to use -- develop and use  
7 "suitable methods to detect impurities when  
8 developing, and making changes to,  
9 manufacturing processes."  
10 You agree with that statement,  
11 right?  
12 A. If during that period, right,  
13 during that initial development time, if  
14 someone, you know, involved in -- you know,  
15 in that, you know, development of that  
16 process, yeah, if they knew, they would  
17 develop a suitable method.  
18 Q. And you also agree that "If new  
19 or higher levels of impurities are detected,  
20 you should fully evaluate the impurities and  
21 take action to ensure the drug is safe for  
22 patients"?  
23 You agree with that statement,  
24 right?

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1 A. As I said, if it's a general  
2 statement, right. You know, for any -- like  
3 a regular, you know, impurity that really  
4 being, you know, appropriately detected like  
5 it was any -- like, you know, what we called  
6 a related substance method, you know, you  
7 know, or whether, you know, we will do the  
8 impurity, you know, identifications. I  
9 mean...  
10 Q. ZHP was required to fully  
11 evaluate the impurities and take action to  
12 ensure that the valsartan was safe for  
13 patients. That you'll agree with, right?  
14 A. Again, you know, if we knew at  
15 the time, you know, yeah, we will do that,  
16 yes.  
17 Q. Well -- rephrase.  
18 MR. SLATER: You know what?  
19 Now we can break.  
20 MR. GALLAGHER: Okay.  
21 MR. SLATER: Off the record.  
22 THE VIDEOGRAPHER: The time  
23 right now is 1:07 p.m. We're now off  
24 the record.

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1 (Whereupon, the deposition was  
2 adjourned.)  
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**CERTIFICATE**

I, MAUREEN O'CONNOR POLLARD, Registered Diplomat Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, MIN LI, Ph.D., was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

\_\_\_\_\_  
 MAUREEN O'CONNOR POLLARD  
 NCRA Registered Diplomat Reporter  
 Realtime Systems Administrator  
 Certified Shorthand Reporter  
 Notary Public

Dated: April 20, 2021

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**INSTRUCTIONS TO WITNESS**

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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**ERRATA**

PAGE	LINE	CHANGE
1	_____	_____
2	_____	_____
3	_____	_____
4	_____	_____
5	REASON: _____	_____
6	_____	_____
7	REASON: _____	_____
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15	REASON: _____	_____
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19	REASON: _____	_____
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21	REASON: _____	_____
22	_____	_____
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**ACKNOWLEDGMENT OF DEPONENT**

I, \_\_\_\_\_, do  
 Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

\_\_\_\_\_  
 Min Li, Ph.D.                      Date

Subscribed and sworn  
 To before me this  
 \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

My commission expires: \_\_\_\_\_

\_\_\_\_\_  
 Notary Public

1	LAWYER'S NOTES		
2	PAGE LINE		
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